



Queensland  
Government

**Metro North**  
Hospital and Health Service

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

Enquiries to: Ann-Maree Gordon  
Coordinator  
Telephone: 07 3646 5490  
File Ref: HREC/2019/QRBW/59234  
Email: [RBWH-Ethics@health.qld.gov.au](mailto:RBWH-Ethics@health.qld.gov.au)

Dr Nicole Marsh  
Nursing and Midwifery Research Centre  
Level 2, Building 34  
Royal Brisbane & Women's Hospital  
Herston Qld 4029

Dear Dr Marsh,

**Re: Ref N<sup>o</sup>: HREC/2019/QRBW/59234: COmparing the use of Midline Catheters versus Peripherally Inserted Central CATHeters for patients requiring peripherally Compatible Therapies: A randomised controlled trial (the COMPACT 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 11 November 2019.

I am pleased to advise that this research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)* and that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

**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>
Cover Letter		28 October 2019
COMPACT Trial Protocol	1.0	28 October 2019
Participant Consent Form	1.0	28 October 2019
Substitute Decision Maker Consent Form	1.0	28 October 2019
REDCap Data Collection Sheet		28 October 2019
BARD® Power Midline™ Catheter – Instructions for Use		

<i>Document</i>	<i>Version</i>	<i>Date</i>
Griffith University/Menzies Health Institute Queensland Capacity Grants Scheme Application Form		
ARTG Certificate: Bard Australia Pty Ltd – Catheter, intravascular, general-purpose (Peripheral vascular infusion / aspiration catheter)		08 October 2014
Curriculum Vitae of Ms Emily N Larsen		
Curriculum Vitae of Catherine O'Brien		
Curriculum Vitae of Peter Anthony Groom		
Curriculum Vitae of Tricia Kleidon		
Response to request for further information		29 November 2019
HREA	Nov ver 2	29 November 2019
Participant Information Sheet	1.1	19 November 2019
Participant Revocation of Consent Form	1.0	19 November 2019
Substitute Decision Maker Information Sheet	1.1	19 November 2019
Substitute Decision Maker Revocation of Consent Form	1.0	19 November 2019
Unimutual Limited Professional Liability Protection for the period 01.11.2019 to 31.10.2020		01 November 2019
Unimutual Limited General and Products Liability Protection for the period 01.11.2019 to 31.10.2020		01 November 2019

Ongoing approval is for the duration of the project, conditional on:

1. In accordance with Section 5.5.6 (b) of the National Statement, the Principal Investigator will report to the HREC annually (**Due by 30 April each year**) in the specified format with a final report to be submitted on completion of the study.  
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project, in the specified format, including:
  - a. Unforeseen events that might affect continued ethical acceptability of the project.
  - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
3. Amendments to the research project are to be submitted to the HREC for review. Amendments should be reflected in a cover letter from the Principal Investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Further advice on submitting amendments is available from:  
<https://metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting>

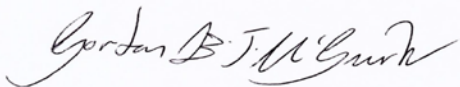
4. The Principal Investigator will notify the HREC if the project is discontinued at the participating site(s) with reasons provided.
  5. If additional sites are engaged prior to the commencement of, or during the research project, the Principal Investigator is required to notify the HREC. Notification of the withdrawn sites should also be provided to the HREC in a timely fashion accompanying a close out report for that site.
- **Please advise the HREC of the date you commence the research project for the approved site(s) using the Notification of Commencement Form:**  
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
  - The 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 nominated participating site for this project is:**

- Royal Brisbane & Women's Hospital

The Royal Brisbane & Women's Hospital Human Research Ethics Committee wishes you every success in your research.

Yours sincerely,



Dr Gordon McGurk  
**Chairperson RBWH Human Research Ethics Committee**  
[Metro North Hospital and Health Service](#)  
04 December 2019

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.