



Queensland
Government

Metro North
Hospital and Health Service

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

Enquiries to: Coordinator
Telephone: 07 3646 5490
File Ref: HREC/2018/QRBW/48811
Email: RBWH-Ethics@health.qld.gov.au

Prof Claire Rickard
School of Nursing and Midwifery
Griffith University
170 Kessels Road
Nathan Qld 4111

Dear Professor Rickard,

Re: Ref N^o: HREC/2018/QRBW/48811: Controlling device occlusion by needleless connector design. A pilot 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 10 December 2018. 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:

Document	Version	Date
Cover Letter		23 November 2018
HREA		24 November 2018
Funding approval from Round Four Nursing and Midwifery Research Fellowships		27 March 2017

<i>Document</i>	<i>Version</i>	<i>Date</i>
Letter of Support from Nursing and Midwifery Research Centre		24 November 2018
Summary for ARTG Entry for Neutral-pressure needleless valve-connector		<i>Effective date:</i> 17 April 2015
MicroClave® Clear Brochure		
Confirmation of Protection – Professional Liability Protection for the period 01.11.2018 to 31.10.2019		01 November 2018
Confirmation of Protection – General and Products Liability Protection for the period 01.11.2018 to 31.10.2019		01 November 2018
Curriculum Vitae of Professor Claire Rickard		
Response to request for further information		18 December 2018
Protocol	1.1	18 December 2018
Participant Information Sheet & Consent Form	1.1	18 December 2018
REDCap eCRF		19 December 2018

Approval of this project from the RBWH HREC is valid from **20.12.2018** to **20.12.2021** 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 **20.12.2019** 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/metro-north/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](mailto:hbrec@rbwh.org.au) 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/metro-north/research/ethics-governance/hrec-approval/membership/default.asp>.

The RBWH HREC wishes you every success in your research.

Yours sincerely,



Dr Gordon McGurk
Chairperson RBWH Human Research Ethics Committee
Metro North Hospital and Health Service
20.12.2018

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.