



Queensland
Government

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

Metro North
Hospital and Health Service

Enquiries to: Ann-Maree Gordon
Coordinator
Telephone: 07 3646 5490
File Ref: HREC/2019/QRBW/54836
Email: RBWH-Ethics@health.qld.gov.au

Ms Cara Masterson
Physiotherapy Department
Level 2, Ned Hanlon Building
Royal Brisbane & Women's Hospital
Herston Qld 4029

Dear Ms Masterson,

Re: Ref N^o: HREC/2019/QRBW/54836: Hydrotherapy in the management of persistent pelvic pain: 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 12 August 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		25 July 2019
Aquatic Physiotherapy Referral	V3.00 – 01/2019	
Australian Pelvic Floor Questionnaire	V1.00 – 06/2014	
Physiotherapy Pelvic Pain Assessment	V1.00 – 08/2017	
Form for Withdrawal of Participation	1	25 July 2019
Patient Experience & Satisfaction Survey – Control Group	1	25 July 2019

<i>Document</i>	<i>Version</i>	<i>Date</i>
Patient Experience & Satisfaction Survey – Intervention Group	1	25 July 2019
Physiotherapy Screening Clinic – Patient Questionnaire	1	25 July 2019
Curriculum Vitae of Cara Masterson		
Curriculum Vitae of Emily Edwards		
Curriculum Vitae of Janene Stephens		
Curriculum Vitae of Jennifer Boyce	July 2019	
Curriculum Vitae of Jennifer Paratz		
Curriculum Vitae of Lorelle Hawes		
Curriculum Vitae of Melissa Webber		
Curriculum Vitae of Michelle Cottrell		
Response to request for further information		30 August 2019
HREA	Aug ver 3	30 August 2019
Study Protocol	2	30 August 2019
Participant Information Sheet & Consent Form	2	30 August 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.

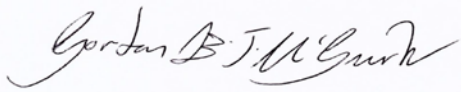
5. If additional sites are engaged prior to the commencement of, or during the research project, the Principal Investigator is required to notify the HREC. Notification of the withdrawn sites should also be provided to the HREC in a timely fashion accompanying a close out report for that site.
- **Please 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
03 September 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.