



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

**Metro North
Hospital and Health Service**

Enquiries to: Ann-Maree Gordon
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File Ref: HREC/16/QRBW/36
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Mr Mahender Haresh Samtani
Physiotherapy Department
Level 2, Ned Hanlon Building
Royal Brisbane & Women's Hospital
Herston Qld 4029

Dear Mr Samtani,

Re: Ref N^o: HREC/16/QRBW/36: Comparative study between two currently utilised approaches for Physiotherapy management for low back pain patients presenting to the emergency department

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 08 February 2016. 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, Qld

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		15 January 2016
Application: NEAF (<i>Submission Code: AU/1/E0B327</i>)	2.2 (2014)	23 January 2016
The McKenzie Institute Lumbar Spine Assessment		
Oswestry Low Back Pain Disability Questionnaire		
The Roland-Morris Low Back Pain and Disability Questionnaire		
Visual Analogue Pain Scale		
Curriculum Vitae of Mahender Samtani		
Response to Request for Further Information		07 April 2016
Curriculum Vitae of Venkat Ramana Acholi		
Response to Request for Further Information		22 May 2016
Protocol	5	17 May 2016
Participant Information Sheet	3	17 May 2016
Participant Consent Form	3	18 May 2016
Form for Withdrawal of Participation	3	17 May 2016
Home Exercise Sheet Type I	2	17 May 2016
Home Exercise Sheet Type II	2	17 May 2016
Patient Home Exercise Checklist	2	17 May 2016
Curriculum Vitae of Janelle Heine		

Approval of this project from the RBWH HREC is valid from **23.05.2016** to **23.05.2019** 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 <http://www.health.qld.gov.au/rbwh/research/hrec.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 <http://www.health.qld.gov.au/rbwh/research/hrec.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 **23.05.2017** and a final report is to be submitted on completion of the study. These instructions can be found at http://www.health.qld.gov.au/ohmr/html/regu/reporting_templates.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 <http://www.health.qld.gov.au/rbwh/research/hrec.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 <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.

The RBWH HREC wishes you every success in your research.

Yours sincerely,



Dr Conor Brophy
Chairperson RBWH Human Research Ethics Committee
Metro North Hospital and Health Service
23.05.2016

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.