



Office of the Human Research Ethics Committee
The Park – Centre for Mental Health
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QLD 4108

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Our Ref: [07-17]
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Prof Sandy Brauer
The University of Queensland
School of Health & Rehabilitation
St Lucia
QLD 4072

Dear Prof Brauer,

HREC reference number: **HREC/17/QWMS/13**
Project title: **Informing state-wide policy on the use of non-slip socks as an inpatient fall prevention measure: A cluster randomized controlled trial and economic evaluation**

Thank you for submitting the above project for ethical and scientific review. This project was considered under the Low and Negligible Risk application process by selected members of the West Moreton Hospital and Health Service (WMHHS) Human Research Ethics Committee.

I am pleased to advise that this Low and Negligible Risk application has been granted approval.

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 (updated May 2015)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

The documents reviewed and approved include:

Document	Version	Date
NEAF Application	AU/1/C95C216	08/03/2017
Protocol	1	06/03/2017
Staff Information Sheet	1	06/03/2017
Waiver of consent		

Please note the following conditions of approval:

1. 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. Serious Adverse Events must be notified to the Committee as soon as possible. In addition the Investigator must provide a summary of the adverse events, in the specified format,

including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.

2. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Please contact the Research Ethics and Governance Officer if you require further information on submitting project amendments.
3. Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office (by-passing the HREC). Please contact the Research Ethics and Governance Officer if you require clarification on amendment submission requirements.
4. Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the Research Ethics and Governance Officer. These should include a cover letter from the Principal Investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
5. The HREC is to be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
6. The Principal Investigator will provide a progress report to the HREC annually and at completion of the study, in the format as attached.
7. The Hospital and Health Service Administration, the Research Ethics and Governance Officer and the Human Research Ethics Committee, may inquire into the conduct of any research or purported research being conducted on hospital premises or claiming any association with WMHHS, whether approved or not, and regardless of the source of funding.

HREC approval is valid for **three years** from the date of this letter.

Should you have any queries about the HREC's consideration of your project please contact Alison Bowers Research Ethics and Governance Officer. The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

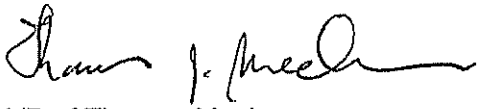
You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the WMHHS CE or Delegate has been obtained by the Research Ethics and Governance Officer.

To enable to the Research Ethics and Governance Officer to obtain authorisation for the study to commence, you are required to submit a completed Site Specific Assessment (SSA) form to the Research Ethics and Governance Officer.

Please contact Alison Bowers, Research Ethics and Governance Officer on 07 3271 8656 or Sharleen.Young@health.qld.gov.au for SSA assistance and guidance.

The HREC wishes you every success in your research.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Thomas J. Meehan', written in a cursive style.

A/Prof Thomas Meehan
Chair

19/05/17

Human Research Ethics Committee - EC00184

