

Ethics Status – Approved

Research Governance Status – Approved

29 May 2017

Ms Catherine Senserrick
Physiotherapist
Peter James Centre
321-345 Burwood Highway,
BURWOOD EAST VIC 3151
Via Email

HREC Reference Number: HREC/16/EH/191
Eastern Health Site Reference Number: E21-2016

Study Title: A new model of physiotherapy rehabilitation to improve outcomes after hip fracture

Further to our letter of 10 February 2017 and responses received from the research team, we are pleased to advise that the above study has received full ethical approval from the Eastern Health Human Research Ethics Committee (HREC) and full governance approval from the Office of the Chief Executive Officer or delegate at Eastern Health and may commence at the nominated site.

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) (**National Statement**). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (**NHRMC**) National Statement and all subsequent updates.

HREC Final Approval Date: 22 May 2017

Research Governance Approval: 25 May 2017

Ethical approval for this project applies at the following Eastern Health campus: Peter James Centre.

Approved Documents:

The following documents have been reviewed and approved by the HREC:

Document	Version	Dated
NEAF Application	AU/1/99DD213	15 May 2017
Victorian Specific Module	Jan 2015	21 November 2016
Protocol	3	23 May 2017
Hip Fracture Data Collection Form	Original	21 November 2016
Master Participant Information Statement and Consent Form	2	22 March 2017
Master Copy PICF Person Responsible	2	22 March 2017

The following documents have been reviewed and approved by the Office of Research and Ethics on behalf of Eastern Health Office of the Chief Executive (for Governance):

Document	Version	Dated
Site Specific Assessment Form	AU/5/B9DD211	15 May 2017

Approval is subject to:

1. The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement on Ethical Conduct in Human Research (updated March 2014).
2. Immediate notification to the Research Governance Unit of any serious adverse events on participants.
3. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project.
4. Notification of any changes to personnel on the study.
5. Notification and reasons for ceasing the project prior to its expected date of completion.
6. Notification of approved amendments to the study.
7. Submission of an annual report due on 14 February each year for the duration of the study (report template is [here](#)).
8. Submission to the HREC of any proposed modifications to the project or documents as approved by the HREC and noted above.
9. Submission of a final report and papers published on completion of the project.
10. Projects may be subject to an audit or any other form of monitoring by the Research Governance and Ethics Office at any time.

Confidentiality, Privacy & Research:

Research data stored on personal computers, USBs and other portable electronic devices must not be identifiable. No patients' names or UR numbers must be stored on these devices. Electronic storage devices must be password protected or encrypted. The conduct of research must be compliant with the conditions of ethics approval and Eastern Health policies.

Publications:

It is very important that the role of Eastern Health is acknowledged in publications.

Composition of the HREC

We confirm at the meetings at which the above project was considered, the Committee fulfilled the requirements of the NHMRC National Statement in that it contained men and women encompassing different age groups and included people in the following categories:

HREC Members

- Chairperson
- Lay Man
- Lay Woman
- Lawyer
- Person/s fulfilling a Pastoral Care Role
- Person/s with Counselling Experience
- Person/s with Current Research Experience

Please quote the reference number **E21 - 2016** in all future correspondence.

Eastern Health HREC wishes you and your colleagues every success in your research.

Yours sincerely



Natasha Savvides
Research Governance and Ethics Officer
Direct Line: 03 9895 3380

On behalf of

1. Eastern Health Human Research Ethics Committee (Ethics Approval)
2. Executive Director Research and Medical Services (Site Authorisation)

cc Professor Nicholas Taylor - nicholas.taylor@easternhealth.org.au
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