Metro South Health

Enquiries to: Metro South
Human Research Ethics Committee
Phone: 07 3443 8049
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HREC Ref: HREC/18/QPAH/38
E-mail: Ethicsresearch.pah@health.qld.gov.au

Dr Tina Skinner
Senior Lecturer
School of Human Movement and
Nutrition Sciences
University of Queensland

Dear Dr Skinner,

HREC Reference number: HREC/18/QPAH/38
Project Title: An evidence-based intervention ("Fit for Treatment") to prevent taxane-induced neurotoxicity in breast cancer patients: An effectiveness-implementation hybrid study

Thank you for submitting the above research protocol to the Metro South Human Research Ethics Committee for ethical and scientific review. This protocol was first considered by the Human Research Ethics Committee (HREC) at the meeting held on 6 February 2018.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the Metro South Chief Executive or Delegate of that site has been obtained.

A copy of this approval must be submitted to the Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the Chief Executive or Delegate to conduct this research at the Princess Alexandra Hospital.

If this study currently receives grant funding, please remember to forward a copy of this approval letter to the relevant Grants Office of the Administering Institution(s) for the grant.

I am pleased to advise you that the research protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* and ethical approval has been granted. The documents reviewed and approved include:

Document	Version	Date
MSF31 Submission checklist form		17 January 2018
Human Research Ethics Application – Submission Code: AU/1/E47334		16 January 2018
Project Description	1.1	2 April 2018
RCT Participant Information Consent form	1.1	2 April 2018
Situational Appraisal Participant Information and Consent form	1.0	11 January 2018
FACT-Cog	3	2016
FACT-G	4	16 November 2007
Chemotherapy Induced Peripheral Neuropathy Assessment Tool (CIPNAT)	1	n.d.
EORTC QLQ-C30	3	1995
Test Preparation Survey	1.0	3 January 2018
Testing Session 1 - Pre-Test Preparation Guidelines	1.0	3 January 2018
Testing Session 2 – Pre-test Preparation Guidelines	1.0	3 January 2018
ActiGraph and Physical Activity Diary	1.0	27 December 2017

Participant Recruitment Flyer	1.0	11 January 2018
Neuropathy Body Chart	1.0	15 January 2018
Borg's Rating of Perceived Exertion	1.0	27 December 2017
Physical Activity and the Cancer Patient		4 January 2018
Letter in response to HREC comments		3 April 2018

This HREC approval is valid from 4 April 2018 until 4 April 2021.

Please note the following conditions of approval:

1. The researcher must provide an annual report to the HREC and a final report on completion of the study, in the specified format. Approval is contingent upon submission of this.
2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol. Serious Adverse Events must be notified to the HREC 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 the event.
3. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review. Amendments should accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Hard copies of the cover letter and all relevant updated documents, with *tracked changes*, must also be submitted to the HREC office as per standard HREC SOP.
4. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
5. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
6. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically (track changes) and in hard copy (final clean copy) to the HREC Coordinator. 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.
7. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
8. The Principal Investigator will provide at least, an annual report to the HREC on the anniversary of the approval and at completion of the study in the specified format.
9. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.
10. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

Should you have any queries about the HREC's consideration of your protocol please contact the Metro South HREC Office on 07 3443 8049.

Please note that the Metro South 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), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition (Attachment I).

Once authorisation to conduct the research has been granted, please complete the Commencement Form (Attached) and return to the Metro South Human Research Ethics Committee.

The Metro South HREC wishes you every success in your research.

Yours sincerely,

Scott Campbell

A/Prof Scott Campbell
A/Chair
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Centres for Health Research
Princess Alexandra Hospital

5/6/18