

OFFICE FOR RESEARCH

MELBOURNE HEALTH HUMAN RESEARCH ETHICS COMMITTEE

ETHICAL APPROVAL OF A RESEARCH PROJECT

Professor Jason David Allen
Institute of Sport Exercise and Active Living (ISEAL)
College of Sport and Exercise Science
Victoria University
Ballarat Road
FOOTSCRAY VIC 3011

24 June 2015

Dear Professor Allen,

MH Project Number: 2015.015

Project Title: Optimising clinical and functional outcomes in older adults with CHF using the Peripheral Remodelling through Intermittent Muscular Exercise (PRIME) approach

HREC Approval Date: 23 June 2015

I am pleased to advise that the above project has received ethical approval.

Participating Sites:

- Victoria University/Western Health's Centre for Health, Research and Education

Approved Documents:

- Research Proposal, Version 6, dated 14 May 2015.
- Western Health Participant Information and Consent Form, Version 3, dated 22 June 2015.
- Telephone script for contacting referred patients, Version 1, dated 18 May 2015.
- Data Collection Booklet, Version 1, dated 29 April 2015.
- Participant Booklet (KCCQ-12 and CDS 1993)
- Exercise Record Sheet (Prime), Version 1, dated 29 April 2015.
- Exercise Record Sheet (Control), Version 1, dated 29 April 2015.

Site Specific Assessment:

Please note: Please forward this HREC approval certificate to the Director of Research at Western Health together with your Research Governance-Site Specific Assessment application. You cannot commence this study until you have completed all the requirements of the Site Specific Assessment and have received written approval to conduct your research project at Western Health.

Conditions of Ethics Approval:

The Melbourne Health HREC operates and is constituted in accordance with the National Statement on Ethical Conduct in Human Research 2007.

In order to comply with the National Statement on Ethical Conduct in Human Research 2007, Guidelines for Good Clinical Research Practice and Melbourne Health Research Policies and Guidelines you are required to:

- Submit a copy of this letter to the Radiation Safety Officer (RSO) at Western Health, for addition of the project to the Licence for Research Involving Human Volunteers held by the Department of Human Services Radiation Safety Section Radiation Safety Licence (if your project involves exposure to ionising radiation). Note: You cannot commence the project until you have received notification from the RSO that the project has been added to the Licence;
- Notify the HREC of the actual start date of the project;
- Submit to the HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure;
- Notify the HREC of any adverse events in accordance with the Melbourne Health Guidelines for Monitoring and Reporting of Safety in Clinical Trials Involving Therapeutic Products and Other Clinical Research, July 2009;
- Notify the HREC of any unforeseen events;
- Notify the HREC of your inability to continue as Principal Investigator or any other change in research personnel involved in the project;
- Notify the HREC if a decision is taken to end the study prior to the expected date of completion or failure to commence the study within 12 months of the HREC approval date;
- Notify the HREC of any other matters which may impact the conduct of the project.
- If the study is a clinical trial, Melbourne Health requires registration of clinical trials in a public trials registry at or before the time of first patient enrolment as a condition of consideration for publication, in accordance with ICMJE
<http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>

Reporting

You are required to submit to the HREC:

- An Annual Progress Report every 12 months (or more frequently as requested by the reviewing HREC) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report in a timely manner; and
- A comprehensive Final Report upon completion of the project.

The HREC may conduct an audit of the project at any time.

Please refer to the Office for Research website to access forms such as the Amendment Form, Annual Report/Final Report Form, Guidelines for Monitoring and Reporting of Safety in Clinical Trials Guidelines and Adverse Event Report Forms, and other information and news concerning research at Melbourne Health:

<http://www.mh.org.au/www/342/1001127/displayarticle/1001352.html>

A list of those HREC members present at the review of this project can be obtained from the above website.

Yours sincerely



Ms. Jessica Turner
Manager - Human Research Ethics Committee

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