PO Royal Melbourne Hospital
Parkville Victoria 3050
Telephone 61 3 9342 8530
Facsimile 61 3 9342 8548
Email: research@mh.org.au
Website: http://research.mh.org.au
ABN 73 802 706 972

MELBOURNE HEALTH

OFFICE FOR RESEARCH

MELBOURNE HEALTH HUMAN RESEARCH ETHICS COMMITTEE
ETHICAL APPROVAL OF A RESEARCH PROJECT

Prof John Wark
Department of Medicine
Royal Melbourne Hospital
Grattan Street
PARKVILLE VIC 3050

25th August 2014

Dear Prof Wark,

MH Project Number: 2014.143

Project Title: Peripheral quantitative computed tomography (pQCT) measures contribute to the understanding of bone fragility in older patients with low-trauma fracture

HREC Approval Date: 25th August 2014

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

Participating Sites:

- Royal Melbourne Hospital

Approved Documents:

- Study Protocol Version 2.0 dated 19th August 2014
- Participant Information and Consent Form Version 2 dated 19th August 2014
- Diagnostic Medical Physics Assessment – Royal Melbourne Hospital

Site Specific Assessment:

Please note: You cannot commence this study until you have completed all the requirements of the Site Specific Assessment and have received the "Approval to Conduct a Research Project at Melbourne Health" certificate.

Conditions of Ethics Approval:

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 Melbourne 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 unforseen 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.

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