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Chair**
Professor of Public Health &
Community Medicine

**Dr Jim Hazel
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Medical Graduate - Endocrinologist

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Catholic Chaplain

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Clinical Trial Coordinator

Mrs Patricia Fa
Clinical Trials Pharmacist

Mr John Fisher
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Dr Clement Loy
Medical Graduate - Neurologist

Mr John McLeod
Layman

Mrs Janette Parry
Laywoman

Mr John Shaw
Layman

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Medical Graduate - Surgeon

Dr Lynn Sinclair
Clinical Nurse Consultant

Dr Howard Smith
Medical Graduate - Endocrinologist

Prof Shih-chang (Ming) Wang
Medical Graduate - Radiologist

Ms Shane Waterton
Laywoman

Ms Christine Wearne
Clinical Psychologist

Our Ref: **HREC2013/12/2.5(3851) AU RED HREC/13/WMEAD/365**

6 March 2014

A/Prof Grahame Elder
Department of Renal medicine
Westmead Hospital

Dear A/Prof Elder

Project title: 'A pilot study to assess bone mineral density (BMD) by digital X-ray radiogrammetry (DXR) in women undergoing mammography and comparison with BMD by dual energy X-ray absorptiometry (DXA)'

Thank you for your letter dated 25 February 2014 addressing the matters raised in the HREC's letter dated 4 February 2014 following single ethical review of the above project at its meeting held on 28 January 2014.

This HREC has been accredited by the NSW Department of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the HREC has now granted ethical approval of this **single site** research project to be conducted at:

- Westmead Hospital - Chief Investigator A/Prof Grahame Elder

The following documentation has been reviewed and approved by the HREC:

- NEAF submission code AU/1/31F4110
- Protocol Version 1 dated 15 October 2013
- Revised Participant Information and Consent Form Version 2 dated 6 March 2014
- Patient Questionnaire, version 1, dated 14 October 2013

HUMAN RESEARCH ETHICS COMMITTEE

Research Office, Room 1072, Level 1, Education Block
Westmead Hospital, Hawkesbury & Darcy Roads, Westmead NSW 2145
Telephone 02 9845 8183 Facsimile 02 9845 8352
Email: WSLHD-ResearchOffice@health.nsw.gov.au

WESTERN SYDNEY LOCAL HEALTH DISTRICT
ABN 48 702 394 764

WSLHD Office, Westmead Hospital Campus
Institute Road, Westmead NSW 2145
PO Box 533, Wentworthville NSW 2145
Telephone 02 9845 5555

Please note the following conditions of approval:

- The Chief Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- The Chief Investigator will immediately report any protocol deviation / violation, together with details of the procedure put in place to ensure the deviation / violation does not recur.
- Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, must be provided to the HREC to review in the specific format. Copies of all proposed changes must also be provided to the relevant research governance officer.
- The HREC must be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
- The Chief Investigator must provide an annual report to the HREC and a final report at completion of the study, in the specified format. HREC approval is valid for 12 months from the date of this letter. Continuation of this approval beyond the initial 12 month period is contingent upon submission of an annual report each year. A copy of the Annual / Final Research Report Form can be obtained electronically from the Research Office on request.
- It should be noted that compliance with the ethical guidelines is entirely the responsibility of the Chief Investigator.

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 Chief Executive or delegate of that site has been obtained. Copies of this letter, together with any approved documents as enumerated above, must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any queries about the HREC's Terms of Reference, Standard Operating Procedures or membership, please contact the HREC Executive Officer through the Research Office on 9845 8183 or emailing researchoffice@swahs.health.nsw.gov.au.

In all future correspondence concerning this study, please quote approval number **HREC2013/12/2.5(3851) AU RED HREC/13/WMEAD/365**

The HREC wishes you every success in your research.

Yours sincerely



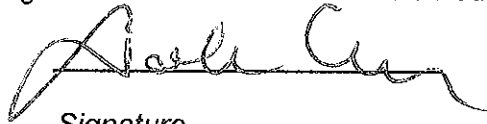
Mrs Kellie Hansen
Acting Research Ethics Manager
WSLHD Research & Education Network

cc Ms Margaret Piper, Research Governance Officer

Please complete the boxes below and return a copy of this page only to the WSLHD Research Office:

- I acknowledge and accept the conditions of ethical approval listed above
- I will not commence this project at any site until separate written authorisation from the Chief Executive or delegate of that site has been obtained

Graham Ewer



11/3/14

Printed Name
Chief Investigator

Signature

Date