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Medical Graduate – Neurologist

Mrs Patricia Fa

Clinical Trials Pharmacist

HREC Committee Members:

Dr Grahame Ctercteko

Medical Graduate – Colorectal Surgeon

Mr John Fisher

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Mr John McLeod

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Mr Sean Mungovan

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Prof Ramon Shaban

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Dr Tony Skapetis

Dental Graduate

Dr Howard Smith

Medical Graduate – Endocrinologist

Ms Jennifer Sullivan

Layperson

Dr Christine Wearne

Clinical Psychologist

Ms Sarah Melov

Clinical Midwife Consultant

Prof Vicki Flood

Allied Health

Ms Elizabeth Tran

Investigational Drug Pharmacist

Research Office File No: **(5996)**

HREC Ref: 2 0 1 8 /ETH00734

SSA Ref:

7 June 2019

Prof Grahame Elder
Department of Renal Medicine
Westmead Hospital

Dear Prof Elder

Project title: A randomised controlled pilot study of bisphosphonate therapy to improve the bone density of patients on dialysis

Thank you for your correspondence addressing the matters raised in the HREC's letter dated 15 March 2019 following single ethical review of the above project at its meeting held on 12 March 2019.

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.

This proposal meets the requirements of the National Statement and I am pleased to advise that the HREC has now granted ethical approval of this research project to be conducted by you at:

- Auburn Hospital – Principal Investigator Prof Grahame Elder
- Blacktown Hospital – Principal Investigator Prof Grahame Elder
- Westmead Hospital – Principal Investigator Prof Grahame Elder

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

- HREA 2018/ETH00734 version 3 dated 5 June 2019
- Protocol, version 1 dated 4 February 2019
- Participant Information Consent Form Main study version 2, dated 7 June 2019
- Data Collection Sheet version 2 dated 30 May 2019
- Prescribing Information Actonel
- Radiation Safety Report dated 15 March 2019

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.

HUMAN RESEARCH ETHICS COMMITTEE

Research Office, Level 2, REN Building

Westmead Hospital, Hawkesbury & Darcy Roads, Westmead NSW 2145

Telephone 02 8890 9007 Facsimile 02 9845 9636

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 8890 5555

- 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 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 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 Coordinating 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 granted for a period of 12 months and ongoing approval is contingent upon annual submission. Annual Reports for all studies should be submitted in November, they will be processed and presented to the HREC at their January meeting. 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 investigators.

You are reminded that this letter constitutes *ethical approval only*. You must not commence this research project until separate authorisation from the Chief Executive or delegate has been obtained. Copies of this letter, together with any approved documents as enumerated above, must be forwarded to the Research Governance Officer as part of the Site Specific Assessment (SSA) application.

In all future correspondence concerning this study, please quote Research Office File number **(5996)**. The HREC wishes you every success in your research.

Yours sincerely



Mrs Patricia Fa
Secretary
WSLHD Human Research Ethics Committee

cc: Research Governance Officer