

HREC Committee Secretariat:

A/Prof Clement Loy
Medical Graduate – Neurologist

Mrs Patricia Fa
Clinical Trials Pharmacist

HREC Committee Members:

Ms Narelle Bell
Lawyer

Dr Grahame Ctercteko
Medical Graduate – Colorectal Surgeon

Prof Angus Dawson
Professor of Bioethics

Mr John Fisher
Lawyer

Mr John McLeod
Layman

Mr Sean Mungovan
Physiotherapist

Mrs Janette Parry
Laywoman

Dr Christopher Ryan
Medical Graduate - Psychiatrist

Mrs Katherine Schaffarczyk
Nurse Educator

Prof Ramon Shaban
Nursing – Community Health

Dr Tony Skapetis
Dental Graduate

Dr Howard Smith
Medical Graduate – Endocrinologist

Ms Jennifer Sullivan
Laywoman

Ms Shane Waterton
Laywoman

Dr Christine Wearne
Clinical Psychologist

Mrs Christina Whitehead
Research Co-Ordinator - RN

Research Office File No: **(5764)**

HREC Ref: AU RED HREC/18/WMEAD/280
SSA Ref: AU RED

30 November 2018

Letter amended 3 December 2018

Prof Clara Chow
Westmead Applied Research Centre
Westmead Hospital

Dear Prof Chow

Project title: Atrial Fibrillation and Intensive Blood pressure lowering Pilot Study-AFIB
Prof Clara Chow – Westmead Applied Research Centre – Westmead Hospital

Thank you for your correspondence addressing the matters raised in the HREC's letter dated 1 August 2018 following single ethical review of the above project at its meeting held on 31 July 2018.

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:

- Westmead Hospital

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

- HREA submission code AU/1/8117315
- Protocol, version 1 dated 22 November 2018
- Participant Information Consent Form Main study version 1, dated 27 September 2018
- Feedback Questionnaire version 1 dated 25 August 2018
- Poster version 1 dated 31 May 2018
- Westmead Hospital Clinic brochure, version 1 dated 31 May 2018
- DoseAid Licence to Manufacture Therapeutic Goods

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 **(5764)**. The HREC wishes you every success in your research.

Yours sincerely



Mrs Patricia Fa
Secretary
WSLHD Human Research Ethics Committee

cc: Research Governance Officer