

HREC Committee Secretariat:

A/Prof Clement Lov Medical Graduate - Neurologist

Mrs Patricia Fa Clinical Trials Pharmacist

HREC Committee Members:

Ms Narelle Bell Lawyer

Sr Patricia Bolster RSM Catholic Chaplain

Mrs Therese Burke Clinical Trial Coordinator

Prof Angus Dawson Professor of Bioethics

Mr John Fisher Lawyer

Mr John McLeod Layman

Mrs Janette Parry Laywoman

Dr Christopher Ryan Medical Graduate - Psychiatrist

Mr John Shaw Lavman

<u>Dr Geoff Shead</u> <u>Medical Graduate</u> – Surgeon

Dr Tony Skapetis Dental Graduate

Dr Howard Smith Medical Graduate – Endocrinologist

Ms Shane Waterton Laywoman

Dr Christine Wearne Clinical Psychologist

Mrs Christina Whitehead Research Co-Ordinator - RN Research Office File No: (4127)

HREC Ref: SSA Ref: AU RED HREC/14/WMEAD/412 AU RED SSA/17/WMEAD/38

17 March 2017

A/Prof Victor SC Fung Department of Neurology Westmead Hospital

Dear A/Prof Fung

Research Proposal: A randomized, double-blind controlled study of botulinum toxin treatment in upper limb tremor

We acknowledge Donna Galea's letter dated 3 March 2017 in response to HREC subcommittee's letter dated 16 December 2016.

The HREC Sub Committee 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 Sub Committee has granted ethical approval of the Request for Amendment / Modification for this **single site** research project being conducted at:

Westmead Hospital –Chief Investigator A/Prof Victor SC Fung

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

- Protocol Version 4 dated 1 March 2017
- Participant Consent Form Version 5 dated 1 March 2017
- MIMS Full prescribing information

This amendment has also been reviewed by the Research Governance Officer of Western Sydney Local Health District. Further authorisation of the approved documents is not required for any site that has Research Governance conducted by the WSLHD Research Governance Office.

HREC approval is valid for 12 months from the date of the original approval and continuation of the HREC approval beyond the initial 12 month approval 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.

## **HUMAN RESEARCH ETHICS COMMITTEE**

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WSLHD Office, Westmead Hospital Campus Institute Road, Westmead NSW 2145 PO Box 533, Wentworthville NSW 2145 Telephone 02 9845 5555 We appreciate your keeping us informed and look forward to receiving your next annual report.

Yours sincerely

Mrs Pat Fa Secretary

WSLHD Human Research Ethics Committee