Research Integrity & Ethics Administration
Human Research Ethics Committee

Wednesday, 8 February 2017

Dr Che Fornusek
Exercise Health and Performance; Faculty of Health Sciences
Email: che.fornusek@sydney.edu.au

Dear Che

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

After consideration of your response to the comments raised your project has been approved.

Approval is granted for a period of four years from **08 February 2017** to **08 February 2021**

Project Title: **Hybrid Electrical Stimulation in Persons with Advanced Multiple Sclerosis**

Project No.: **2016/845**

First Annual Report Due: **08 February 2018**

Sites Approved: **University of Sydney, Cumberland Campus**

Authorised Personnel: **Fornusek Che; Mate Suzanne; Barnett Michael; Hoang Phu;**

Documents Approved:

Date Uploaded	Version number	Document Name
11/12/2016	Version 2	Flyer CLEAN
11/12/2016	Version 2	PIS CLEAN
11/12/2016	Version 2	Letter to GP CLEAN
11/12/2016	Version 2	Methodology Outline CLEAN
11/12/2016	Version 1	Adverse Events Log Version 1
11/12/2016	Version 1	Clinical Trial Protocol for Study
25/09/2016	Version 1	Letter to MS Organizations Version 1
18/09/2016	Version 1	Patient Consent Form Version 1

Special Conditions of Approval for Clinical Trials

- Clinical Trials must be registered on a clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). For trials conducted in Australia or New Zealand registration should be on the Australian New Zealand Clinical Trial Registry before recruitment of the first subject (http://www.anzctr.org.au/).

- A trial to be conducted under the Clinical Trials Notification (CTN) scheme should not commence until it has been notified to the Therapeutic Goods Administration (TGA). If your study is sponsored by the University please contact Clinical Trials Governance to arrange submission of your CTN.

- **This letter constitutes ethical approval only.** This project cannot proceed at any site until the necessary research governance authorisation is obtained. If your study is sponsored by the University or is to be conducted on a University of Sydney site you may need to comply with additional University governance requirements prior to commencing. Please contact the Clinical Trials Governance Office at clinicaltrialgovernance.research@sydney.edu.au.

Condition/s of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
  - Serious or unexpected adverse events (which should be reported within 72 hours).
  - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.
- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.
- The Ethics Office may conduct audits on approved projects.
- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

Please contact the Ethics Office should you require further information or clarification.

Sincerely

Professor Glen Davis
Chair
Human Research Ethics Committee

cc. Clinical Trial Governance

THE UNIVERSITY OF SYDNEY

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007) and the NHMRC's Australian Code for the Responsible Conduct of Research (2007).