

**Research Integrity**

Human Research Ethics Committee

Thursday, 24 March 2016

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

Dear Che

I am pleased to inform you that the University of Sydney Human Research Ethics Committee (HREC) has approved your project entitled "**FUNCTIONAL ELECTRICAL STIMULATION CYCLING EXERCISE IN PERSONS WITH SEVERE CEREBRAL PALSY: A PILOT STUDY**".

Details of the approval are as follows:

**Project No.:** 2016/106  
**Approval Date:** 24 March 2016  
**First Annual Report Due:** 24 March 2017  
**Authorised Personnel:** Fornusek Che; Burns Joshua; Zhang Portia; Clarke Jillian; Paget Simon;

**Documents Approved:**

Date Uploaded	Type	Document Name
07/03/2016	Participant Info Statement	PIS Oral Standard Version 2
07/03/2016	Participant Info Statement	PIS Parent Version 2
07/03/2016	Participant Info Statement	PIS Standard Version 2
08/01/2016	Unexpected/Adverse Event form	Adverse Event Form
16/01/2016	Advertisements/Flyer	Advertisement / Flyer
18/01/2016	Other Type	ARTG #205314
08/01/2016	Other Type	Case Report Form
21/01/2016	Other Type	Device information
17/01/2016	Questionnaires/Surveys	Follow up questionnaire
16/01/2016	Other Type	Letter to GP / Specialist for Participant Medical Clearance
16/01/2016	Participant Consent Form	PCF Oral Script
16/01/2016	Participant Consent Form	PCF Parent permission for Adolescent
16/01/2016	Participant Consent Form	PCF Standard
16/01/2016	Recruitment Letter/Email	Recruitment Letter to CP organizations
08/01/2016	Other Instruments/Tools	SF36 Quality of life survey

HREC approval is valid for four (4) years from the approval date stated in this letter and is granted pending the following conditions being met:

**Special Condition/s of Approval**

- The addition of two researchers to the project is noted. Please provide an updated Clinical Trials CV template which includes the additional researchers, Dr Simon Paget and Mrs Jillian Clark.



**Condition/s of Approval**

- Continuing compliance with the National Statement on Ethical Conduct in Research Involving Humans.
- Provision of an annual report on this research to the Human Research Ethics Committee from the approval date and at the completion of the study. Failure to submit reports will result in withdrawal of ethics approval for the project.
- All serious and unexpected adverse events should be reported to the HREC within 72 hours.
- All unforeseen events that might affect continued ethical acceptability of the project should be reported to the HREC as soon as possible.
- Any changes to the project including changes to research personnel must be approved by the HREC before the research project can proceed.
- Note that for student research projects, a copy of this letter must be included in the candidate's thesis.

**Chief Investigator / Supervisor's responsibilities:**

1. You must retain copies of all signed Consent Forms (if applicable) and provide these to the HREC on request.
2. It is your responsibility to provide a copy of this letter to any internal/external granting agencies if requested.

Please do not hesitate to contact Research Integrity (Human Ethics) should you require further information or clarification.

Yours sincerely

**Dr Stephen Assinder**  
**Chair**  
**Human Research Ethics Committee**

**This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.**