

Research Integrity

Human Research Ethics Committee

Friday, 4 March 2016

Dr David Kennedy
Physiotherapy; Faculty of Health Sciences
Email: david.kennedy@sydney.edu.au

Dear David

I am pleased to inform you that the University of Sydney Human Research Ethics Committee (HREC) has approved your project entitled **“Do interventions targeting proprioceptive feedback and exercise improve functional gait and reduce falls and falls risk in people with multiple sclerosis?”**

Details of the approval are as follows:

Project No.: 2016/002

Approval Date: 4 March 2016

First Annual Report Due: 4 March 2017

Authorised Personnel: Kennedy David; Canning Colleen; Mai Sylvia; Hoang Phu; Lord S;

Documents Approved:

<u>Date</u>	<u>Type</u>	<u>Document</u>
23/02/2016	Study Protocol	MS Study Clinical Protocol V3
23/02/2016	Other Type	Declaration of Conformity
23/02/2016	Other Type	WBV TGA Application
23/02/2016	Other Type	WBV brochure to TGA
23/02/2016	Other Type	Brochure 2 for TGA
21/01/2016	Study Protocol	Revised Clinical Trial protocol
21/01/2016	Participant Info Statement	Revised PIS
21/01/2016	Other Instruments/Tools	Falls Diary
21/01/2016	Participant Consent Form	Revised Consent Form
21/01/2016	Participant Info Statement	Revised PIS redlined version
18/01/2016	Other Instruments/Tools	Attachment 4 WBV product information document
13/11/2015	Other Instruments/Tools	Attachment 3 Exercise Protocol Table 1
13/11/2015	Advertisements/Flyer	Advertisement Flyer
13/11/2015	Cover Letter/Correspondence	Attachment 1 MD letter
13/11/2015	Recruitment Letter/Email	Invitation letter
13/11/2015	Other Type	Clinical trials CV template



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:

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

**Professor Glen Davis
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.