

**Subject:** RE: VB 11623: Ethics documents for Studies 2, 3 and 4.  
**Date:** Monday, 23 March 2015 at 4:21:58 PM Australian Eastern Standard Time  
**From:** Research Ethics  
**To:** Vanesa BOCHKEZANIAN  
**CC:** Tony BLAZEVIKCH

Hi Vanesa

**Project 11623 - Effect of a Neuromuscular electrical stimulation (NMES) /vibration driven muscle strength training intervention on muscle force, physical function and health, and quality of life in people with a spinal cord injury**

Thank you for responding to the Committee comments and providing the revised materials for Studies 2 – 4. Ethics approval has now been granted for Studies 2, 3 and 4.

Regards  
Kim

**Kim Gifkins, Research Ethics Officer, Office of Research & Innovation, Edith Cowan University, 270 Joondalup Drive, Joondalup, WA 6027**  
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**From:** Vanesa BOCHKEZANIAN  
**Sent:** Friday, 20 March 2015 5:57 PM  
**To:** Research Ethics  
**Cc:** Tony BLAZEVIKCH  
**Subject:** Re: VB 11623: Ethics documents for Studies 2, 3 and 4.

Dear Kim,

I am attaching a word document with the response to the points from the Ethics Committee. I am also attaching the updated information letters for Studies 2, 3 and 4 as well as the email to participants for Study 2, with the updated information underlined.

Should you need further information please do not hesitate to contact me.

Regards,

Vanesa  
Vanesa Bochkezanian  
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**From:** Research Ethics <[research.ethics@ecu.edu.au](mailto:research.ethics@ecu.edu.au)>

**Date:** Friday, 20 March 2015 10:33 am

**To:** Vanesa Bochkezanian <[v.bochkezanian@ecu.edu.au](mailto:v.bochkezanian@ecu.edu.au)>

**Cc:** Anthony BLAZEVIK <[a.blazevich@ecu.edu.au](mailto:a.blazevich@ecu.edu.au)>, Camila Quel de Oliveira <[cquel@scia.org.au](mailto:cquel@scia.org.au)>, Kierre Williams <[kwilliams@scia.org.au](mailto:kwilliams@scia.org.au)>

**Subject:** RE: VB 11623: Ethics documents for Studies 2, 3 and 4.

Hi Vanesa

**Project 11623 - Effect of a Neuromuscular electrical stimulation (NMES) /vibration driven muscle strength training intervention on muscle force, physical function and health, and quality of life in people with a spinal cord injury**

Thank you for providing the materials for Studies 2 – 4. The material has been reviewed by members of the Ethics Committee and they had the following comments:

These are very exciting and worthwhile studies.

**Information Letters**

The email to participants for Study 2 includes the following information:

we will ask you to fill an spasticity subjective questionnaire in the following hours after days after the session.

The reviewers indicated that this is unclear and needs rewording for clarification.

The second Information Letter for study 3 and 4 in the section Benefits of Study Participation uses the term Physical Therapy. The reviewers indicated that Physiotherapy is the usual term in Australia; Physical Therapy being the American term. Unless there is a specific reason to use Physical Therapy, participants in these studies may be more familiar with the term Physiotherapy.

The reviewers also requested clarification of the approach for warning the participants of the more serious risks of electrical stimulation. The descriptions of the studies include the following potential risks:

Further risks when using electrical stimulation include the development of autonomic dysreflexia (AD), hypotension, muscle damage and prolonged muscle fatigue.

Potential risks when using electrical stimulation in people with SCI are the development of autonomic dysreflexia (AD), which is a life-threatening situation, the development of spasticity, which is the sustained contraction of the muscle and hypotension.

However, Study 2 and Study 3 letters do not mention any of these, and the Study 4 letter does not mention the development of spasticity.

In terms of the brief mention of AD and hypotension in the Study 4 letter, the researcher indicates that the participants are aware of these risks as they encounter them in everyday life. The reviewers do not see a need for an extensive explanation of the risks, but indicated that a brief, clear reference to the fact that they are possible should be included in all the information letters.

Please send your response to these points via email so that I can progress your application.

Regards  
Kim

**Kim Gifkins, Research Ethics Officer, Office of Research & Innovation**, Edith Cowan University, 270 Joondalup Drive, Joondalup, WA 6027  
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**From:** Vanesa BOCHKEZANIAN  
**Sent:** Thursday, 26 February 2015 11:16 PM  
**To:** Research Ethics  
**Cc:** Tony BLAZEVIICH; Camila Quel de Oliveira; Kierre Williams  
**Subject:** VB 11623: Ethics documents for Studies 2, 3 and 4.  
**Importance:** High

Dear Kim,

Hope you are doing fine. I am attaching an updated version of my proposal, we made some changes to the original proposal and we included a 4th Study to obtain more valuable data. I am also attaching Ethics documents, participant's information letters, emails templates and posters for each separate study (2,3 and 4). Finally, I am also attaching the questionnaires and assessment forms. Would you please be able to check that I have all of the information that you need?

Thank you very much!

Kind regards,

Vanesa  
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