

**Research Integrity**

Human Research Ethics Committee

Wednesday, 21 January 2015

Dr Martin Mackey  
Clinical and Rehabilitation Sciences; Faculty of Health Sciences  
Email: martin.mackey@sydney.edu.au

Dear Martin

I am pleased to inform you that the University of Sydney Human Research Ethics Committee (HREC) has approved your project entitled "**Does online psychological intervention improve self-efficacy and disability in people receiving chiropractic treatment for chronic low back pain? A pilot randomised trial**".

Details of the approval are as follows:

**Project No.:** 2014/997

**Approval Date:** 21 January 2015

**First Annual Report Due:** 21 January 2016

**Authorised Personnel:** Mackey Martin; Petrozzi Marco John; Ferreira Paulo; Jones Mairwen; Leaver Andrew;

**Documents Approved:**

Date Uploaded	Type	Document Name
09/01/2015	Advertisements/Flyer	Waiting Room Brochure post HREC comments
11/11/2014	Advertisements/Flyer	Waiting room poster
11/11/2014	Interview Questions	Follow up Form
11/11/2014	Interview Questions	Intake Form
11/11/2014	Other Instruments/Tools	MoodGYM Participant Manual
11/11/2014	Other Instruments/Tools	STarT Screening Tool
11/11/2014	Participant Consent Form	Participant Consent Form
09/01/2015	Participant Info Statement	Participant Info Sheet post HREC comments_pdf
13/11/2014	Questionnaires/Surveys	Work Ability Index
11/11/2014	Questionnaires/Surveys	Pain Self Efficacy Questionnaire (PSEQ)
11/11/2014	Questionnaires/Surveys	Roland-Morris LBP and Disability Questionnaire (RMQ)
11/11/2014	Questionnaires/Surveys	Pain Numeric Rating Scale
11/11/2014	Questionnaires/Surveys	Pain Catastrophizing Scale (PCS)
11/11/2014	Questionnaires/Surveys	Patient Specific Functional Scale
11/11/2014	Questionnaires/Surveys	DASS21

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**

- Please provide clean versions of the amended and approved public documents, ensuring that the page numbering on the revised PIS is correct (final page should be numbered Pg 3 of 3).
- Please note, you are reminded that a trial to be conducted under the CTN Scheme cannot commence until it has been notified to the Therapeutic Goods Administration (TGA) and a copy of the TGA acknowledgment letter has been received by the University of Sydney Ethics Committee.
- You are reminded that all Clinical Trials must comply with requirement to register clinical trials on a publicly accessible clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). This trial will require registration on the Australian New Zealand Clinical Trial register before recruitment of the first subject (<http://www.anzctr.org.au/>). This requirement has been embedded in the University Research Code of Conduct Policy 2013.

### **Condition/s of Approval**

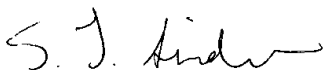
- Continuing compliance with the National Statement on Ethical Conduct in Research Involving Humans.
- Provision of an annual report on this research to the Human Research Ethics Committee from the approval date and at the completion of the study. Failure to submit reports will result in withdrawal of 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.