

Research Integrity

Human Research Ethics Committee

Tuesday, 9 September 2014

Prof Nicholas Glozier

Central Clinical School: Psychological Medicine; Sydney Medical School

Email: nick.glozier@sydney.edu.au

Dear Nicholas

I am pleased to inform you that the University of Sydney Human Research Ethics Committee (HREC) has approved your project entitled "Mindfulness-based stress reduction program for university employees: a pilot study".

Details of the approval are as follows:

Project No.: 2014/649

Approval Date: 9 September 2014

First Annual Report Due: 9 September 2015

Authorised Personnel: Glozier Nicholas; Koncz Rebecca Elizabeth; Wolfenden Fiona;

Documents Approved:

<u>Date</u>	<u>Type</u>	<u>Document</u>
28/07/2014	Other Type	Facilitator information
28/07/2014	Questionnaires/Surveys	K10 - Psychological Distress Questionnaire
28/07/2014	Questionnaires/Surveys	Workplace wellbeing and engagement questionnaire
28/07/2014	Questionnaires/Surveys	Utrecht Work Engagement Scale
22/08/2014	Advertisements/Flyer	Promotional flyer Version 2 21.08.14
22/08/2014	Questionnaires/Surveys	Mindfulness focus group questions
03/09/2014	Participant Info Statement	PIS version 3
03/09/2014	Participant Consent Form	PCF version 3

Special Condition/s of Approval

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.



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.