

ADDRESS FOR ALL CORRESPONDENCE  
RESEARCH ETHICS AND GOVERNANCE OFFICE  
ROYAL PRINCE ALFRED HOSPITAL  
CAMPERDOWN NSW 2050



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REFERENCE: X16-0305 & HREC/16/RPAH/400

31 October 2016

Dr Z McKeough  
Room 0203  
Discipline of Physiotherapy  
University of Sydney  
Cumberland Campus, C42  
PO Box 170  
LIDCOMBE NSW 1825

Dear Dr McKeough,

**Re: Protocol No X16-0305 & HREC/16/RPAH/400 - "A behaviour-change intervention to reduce sitting time in people with chronic obstructive pulmonary disease: a pilot randomised controlled trial"**

The Executive of the Ethics Review Committee, at its meeting of 26 October 2016 considered your correspondence of 20 September 2016. In accordance with the decision made by the Ethics Review Committee, at its meeting of 10 August 2016, ethical approval is granted.

The proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

This approval includes the following:

- NEAF (AU/1/E517211)
- Study Protocol (Version 3, 1 July 2016)
- Safety Protocol (Version 2, 21 July 2016)
- Information for Participants (Master Version 4, 20 July 2016)
- Participant Consent Form (Master Version 1, 1 July 2016)

- Six minute walk test (Master Version 1, 1 July 2016)
- St George Respiratory Questionnaire (Master Version 1, 1 July 2016)
- Sedentary Behaviour Questionnaire (Master Version 1, 1 July 2016)
- Patient Activation Measure (Master Version 1, 1 July 2016)
- Hospital Anxiety and Depression Scare (Master Version 1, 1 July 2016)
- Participant Satisfaction and Burden Survey (Master Version 1, 1 July 2016)
- Readiness for change Assessment Tool (Master Version 1, 1 July 2016)
- Perceived Competence Scale (Master Version 1, 1 July 2016)
- Treatment Self-Regulation Scale (Master Version 1, 1 July 2016)
- Intervention checklist for initial sessions (Master Version 2, 1 July 2016)
- Intervention checklist for follow-up Sessions (Master Version 2, 1 July 2016)
- Participant Workbook (Master Version 1, 1 July 2016)

You are asked to note the following:

- **This letter constitutes ethical approval only.**
- **You must NOT commence this research project at ANY site until you have submitted a Site Specific Assessment Form to the Research Governance Officer and received separate authorisation from the Chief Executive or delegate of that site.**

**On the basis of this ethics approval, authorisation may be sought to conduct this study within any NSW/QLD/VIC/SA/ACT public health organisation and/or within any private organisation which has entered into an appropriate memorandum of understanding with the Sydney Local Health District, Sydney Local Health Network or the Sydney South West Area Health Service.**

The Committee noted that authorisation will be sought to conduct the study at the following sites:

- Royal Prince Alfred Hospital
- Prince of Wales Hospital
- This approval is valid for four years, and the Committee requires that you furnish it with annual reports on the study's progress beginning in **November 2017**. If recruitment is ongoing at the conclusion of the four year approval period, a full re-submission will be required. Ethics approval will continue during the re-approval process.

- This human research ethics committee (HREC) has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review and is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.
- You must immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- You must notify the HREC of proposed changes to the research protocol or conduct of the research in the specified format.
- You must notify the HREC and other participating sites, giving reasons, if the project is discontinued at a site before the expected date of completion.
- If you or any of your co-investigators are University of Sydney employees or have a conjoint appointment, you are responsible for informing the University's Risk Management Office of this approval, so that you can be appropriately indemnified.
- Where appropriate, the Committee recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purposes of conducting this study.

Should you have any queries about the Committee's consideration of your project, please contact me. The Committee's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Sydney Local Health District website.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The Ethics Review Committee wishes you every success in your research.

Yours sincerely,



Sharon Falleiro  
**Executive Officer**  
**Ethics Review Committee (RPAH Zone)**

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