Research Office File No: **(4670)**

HREC Ref: AU RED HREC/16/WMEAD/131
SSA Ref: AU RED SSA/16/WMEAD/140

30 June 2016

Prof John Wheatley
Department of Respiratory Medicine
Westmead Hospital

Dear Prof Wheatley

Project title: 'Randomised contolled trial of a non-pharmacological integrated care intervention to reduce breathlessness in patients with severe or very severe chronic obstructive pulmonary disease (COPD)'

Thank you for your letter dated 27 June 2016 addressing the matters raised in the HREC's letter dated 3 June 2016 following single ethical review of the above project at its meeting held on 31 May 2016.

This HREC has been accredited by the NSW Department of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC 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.*

This proposal meets the requirements of the National Statement and I am pleased to advise that the HREC has now granted ethical approval of this **single site** research project to be conducted at:

- Westmead Hospital – Chief Investigator Prof John Wheatley

The following documentation has been reviewed and approved by the HREC:

- NEAF submission code AU/1/CB45216
- Protocol, version 2, dated 27 June 2016,
- Participant Information and Consent Form, version 2, dated 24 June 2016
- Fact Sheet 1: What is the Breathlessness Clinic?, version 1, dated 16 March 2016

- Fact Sheet 2: What is Breathlessness? version 1, dated 16 March 2016
- Fact Sheet 3: Breathing Techniques, version 1, dated 16 March 2016
- Fact Sheet 4: Positions to ease breathlessness, version 1, dated 16 March 2016
- Fact Sheet 5: Handheld Fan, version 1, dated 16 March 2016
- Fact Sheet 6: Energy Conservation, version 1, dated 16 March 2016
- Fact Sheet 7: Healthy Eating and Breathlessness, version 1, dated 16 March 2016
- Fact Sheet 8: Sleep, version 1, dated 16 March 2016
- Fact Sheet 9: Anxiety, version 1, dated 16 March 2016
- Fact Sheet 10: Relaxation, version 1, dated 16 March 2016
- Fact Sheet 11: Depression, version 1, dated 16 March 2016
- Managing Flare-ups, version 1, dated 16 March 2016
- Maintaining an active lifestyle, version 1, dated 16 March 2016
- Modified Medical Research Council Dyspnoea Scale, version 1, dated 16 March 2016
- ED-5D-5L, version 1, dated 16 March 2016
- HAD Scale, version 1, dated 16 March 2016
- Plan for Breathlessness 1, version 1, dated 16 March 2016
- Plan for Breathlessness 2, version 1, dated 16 March 2016
- Plan for breathlessness 3, version 1, dated 16 March 2016
- EAT-10 a Swallowing Screening Tool, no version or date
- C-MSAS, version 1, dated 16 March 2016
- COPD Assessment Test (CAT), dated February 24, 2012
- Breathlessness Numerical Rating Scale, version 1, dated 16 March 2016
- Walking Diary, version 1, dated 16 March 2016
- Chronic Respiratory Questionnaire (CRQ-Original), Follow Up (Informed) Adminstration, version 7 July 2015
- Chronic Respiratory Questionnaire (CRQ-Original), Interviewer Administered Format, version 7 July 2015

Please note the following conditions of approval:

- The Chief Investigator will 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.
- **For clinical trials of implantable medical devices only** – The Chief Investigator will confirm to the HREC that a process has been established for tracking the participant, with consent, for the lifetime of the device and will immediately report any device incidents to the Therapeutic Goods Administration (TGA).
- The Chief Investigator will immediately report any protocol deviation / violation, together with details of the procedure put in place to ensure the deviation / violation does not recur.
- The Chief Investigator will provide to the HREC in the specific format, proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, must be provided to the HREC to review in the specific format. Copies of all amendments when approved by the HREC must also be provided to the Research Governance Officer.
- The Chief Investigator must notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
- The Coordinating Chief Investigator must provide an annual report to the HREC and a final report at completion of the study, in the specified format. HREC approval is granted for a period of 12 months and ongoing approval is contingent upon annual submission. Annual Reports for all studies should be submitted in November, they will be processed

and presented to the HREC at their January meeting. A copy of the Annual / Final Research Report Form can be obtained electronically from the Research Office on request.

- The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived including
  1. Discussion of relevant aspects of the project with investigators, at any time,
  2. Random inspection of research sites, data or consent documentation,
  3. Interview with research participants or other forms of feedback from them, and
  4. Request and review reports from independent agencies such as a Data Safety Monitoring Board.
- If your research project is an interventional trial, please ensure it is registered on one of the clinical trial registries, eg http://www.actr.org.au.
- It should be noted that compliance with the ethical guidelines is entirely the responsibility of the Chief Investigator.

You are reminded that this letter constitutes *ethical approval only*. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. Copies of this letter, together with any approved documents as enumerated above, must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any queries about the HREC's Terms of Reference, Standard Operating Procedures or membership, please contact the Acting Research Ethics Manager through the Research Office on 9845 8183 or emailing kellie.hansen@health.nsw.gov.au.

In all future correspondence concerning this study, please quote Research Office File Number ***(4670)***

The HREC wishes you every success in your research.

Yours sincerely

Mrs Kellie Hansen
Research Ethics Manager
WSLHD Research & Education Network

cc Ms Margaret Piper, Research Governance Officer