4 September 2017 – revised 20 September 2017
revised 02 February 2018

Dr Cindy Thamrin
Airway Physiology and Imaging Group
Woolcock Institute of Medical Research
Airway Physiology Group (Level 4)
PO Box M77
CAMPERDOWN NSW 2050

Dear Dr Thamrin,

Re: HREC/17/CRGH/177 CH62/6/2017-119
Role of home telemonitoring of lung function using the Forced Oscillation Technique in assessing and predicting asthma control: a pragmatic, observational trial.

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting held on 27 July 2017. This Human Research Ethics Committee (HREC) has been accredited by the NSW Ministry of Health as a lead HREC under the model for single ethical and scientific review.

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.

I am pleased to advise that the proposal meets the requirements of the National Statement on Ethical Conduct in Human Research and final ethical approval has been granted.

The documents reviewed and approved include:

<table>
<thead>
<tr>
<th>IDENTIFICATION NUMBER</th>
<th>DATE</th>
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<tbody>
<tr>
<td>National Ethics Application Form (NEAF)</td>
<td>Submission code AU/1/A7CE24 21/06/2017</td>
</tr>
<tr>
<td>Protocol</td>
<td>Version 1.1 9/08/2017</td>
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<tr>
<td>Product Brochure for Resmon™ PRO FULL Forced Oscillation Technique</td>
<td>-</td>
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<tr>
<td>Master Participant Information Sheet &amp; Consent Form</td>
<td>Version 1.2 14/09/2017</td>
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<tr>
<td>Concord Hospital Airways Clinic Questionnaire</td>
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<td>Advertising Flyer</td>
<td>Version 1.1 14/08/2017</td>
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<td>Asthma Control Questionnaire</td>
<td>- April 2002</td>
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<tr>
<td>Daily Electronic Diary Questionnaire</td>
<td>Version 2.0 09/08/2017</td>
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<tr>
<td>Weekly Questionnaire</td>
<td>Version 1.0 09/08/2017</td>
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</table>
The HREC has provided ethical and scientific approval for the following sites:
1. Concord Repatriation General Hospital
2. Royal Prince Alfred Hospital
3. Royal North Shore Hospital
4. Woolcock Institute of Medical Research

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at Concord Hospital until a Site Specific Application has been reviewed and approved and separate authorisation from the Chief Executive or delegate has been obtained.

Please forward a copy of this letter to all site investigators for submission to the relevant Research Governance Officer.

Please note the following conditions of approval:

1. You 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, (including Serious Adverse Events).
2. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review in the specified format.
3. You will notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
4. You will provide an annual report to the HREC, and at completion of the study in the specified format.
5. You will adhere to the study protocol at all times as failure to do so will invalidate the Indemnity agreement.
6. It is a requirement of ethics approval that before its commencement this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. You are asked to provide details of the Register in which the study has been included and its registration number.
7. 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.

HREC approval is valid for five (5) years subject to the supply of an annual progress report. The first report should be sent to the Concord Hospital Research Office by 30/09/2018.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer - (02) 9767-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the website: www.swahs.nsw.gov.au/concord/ethics.

We wish you every success in your research.

Please quote the above file number in all correspondence.
Yours sincerely,

[Signature]

Professor Andrew McLachlan
Chairman
Sydney Local Health District Human Research Ethics Committee – CRGH

Please complete the boxes below and return a copy of this page to the Concord Hospital Research Office:

☐ I acknowledge and accept the Conditions of Ethical Approval.

☐ I will not commence this project at any site until separate written authorisation from the Chief Executive or delegate of that site has been obtained

Printed Name
Chief Investigator

Signature

Date