

Contact: Sydney Local Health District Human Research Ethics Committee –
CRGH
Concord Repatriation General Hospital (CRGH)
Concord NSW 2139
Telephone: (02) 9767 5622
Email: crgh.ethics@sswahs.nsw.gov.au



CONCORD
REPATRIATION GENERAL
HOSPITAL

Our Ref:

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:

	IDENTIFICATION NUMBER	DATE
National Ethics Application Form (NEAF)	Submission code AU/1/A7CE24	21/06/2017
Protocol	Version 1.1	9/08/2017
Product Brochure for Resmon™ PRO FULL Forced Oscillation Technique	-	-
Master Participant Information Sheet & Consent Form	Version 1.2	14/09/2017
Concord Hospital Airways Clinic Questionnaire	-	-
Advertising Flyer	Version 1.1	14/08/2017
Asthma Control Questionnaire	-	April 2002
Daily Electronic Diary Questionnaire	Version 2.0	09/08/2017
Weekly Questionnaire	Version 1.0	09/08/2017

The HREC has provided ethical and scientific approval for the following sites:

1. Concord Repatriation General Hospital

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

2. Royal Prince Alfred Hospital
3. Royal North Shore Hospital
4. Woolcock Institute of Medical Research

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.sswahs.nsw.gov.au/concord/ethics.

We wish you every success in your research.

Please quote the above file number in all correspondence.

Yours sincerely,



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