

Office for Research

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Government of South Australia

SA Health

Southern Adelaide Local Health Network

Final Approval for Ethics Application

17 May 2018

Dr Sarah Newhouse
Respiratory and Sleep Services SALHN
Level 6
Flinders Medical Centre
Bedford Park
SA 5042

Dear Dr Newhouse,

OFR Number: 28.18
HREC reference number: HREC/18/SAC/31
HREA Application ID: 166762
Project title: A pilot study to assess the impact of obstructive sleep apnea and treatment with continuous positive airway pressure therapy on maternal blood pressure and placental health in severely obese obstetric patients.
Chief Investigator: Dr Sarah Newhouse
Ethics Approval Period: 15th May 2018 – 15th May 2021

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided approval for this application which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*.

You are reminded that this letter constitutes **Ethics** approval only. **Ethics approval is one aspect of the research governance process.**

You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form, has been approved by the Chief Executive or delegate of each site.

Public health sites approved under this ethics application:

- Flinders Medical Centre, SA

The below documents have been reviewed and approved:

- Cover letter 09/03/2018
- HREA v3 14/03/2018
- HREA Project Description v4 17/04/2018
- Participant information sheet and consent form v4 18/04/2018
- Data collection sheet – questionnaire v1 08/03/2018
- SAQLI patient questionnaire v1 14/02/2018
- Schedule of events v1 08/03/2018
- Flyer v2 10/02/2018
- Study database v1 08/03/2018
- Sleep diary v1 08/03/2018
- Further information from researcher (email) 05/04/2018

- Letter of support Philips Sleepeasy Adelaide 04/04/2018
- Response to ethics committee minute 20/04/2018

The below documents have been reviewed and noted:

- Resume S Newhouse
- Resume V Aiyappan
- Sleep disordered breathing in pregnancy. American Thoracic Society. American Journal of Respiratory and Critical Care Medicine volume 190, p1-2 2014.
- Continuous Positive Airway Pressure Therapy in Gestational Diabetes with Obstructive Sleep Apnea: a Randomised Controlled Trial, Sirimon Reutrakul, Department of Medicine, University of Illinois College of Medicine at Chicago.

Terms and Conditions Of Ethics Approval:

It is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5*.

Final ethics approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval only covers the science and ethics component of the application. A SSA will need to be submitted and authorised before this research project can commence at any of the approved sites identified in the application.
2. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
3. Compliance with the *National Statement on Ethical Conduct in Human Research (2007)* & the *Australian Code for the Responsible Conduct of Research (2007)*.
4. To immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.

For any queries about this matter, please contact The Office for Research on
(08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au

Yours sincerely

A handwritten signature in black ink, appearing to read 'Bernadette Richards', written in a cursive style.

A/Professor Bernadette Richards
Chair, SAC HREC