NSW GOVERNMENT Health
South Eastern Sydney Local Health District

HUMAN RESEARCH ETHICS COMMITTEE
Room G71 East Wing
Edmund Blacket Building
Prince of Wales Hospital
RANDWICK NSW 2031
Tel: 02 9382 3587 Fax: 02 9382 2813
RSOSESLHD@SESIAHS.HEALTH.NSW.GOV.AU
http://www.seslhd.health.nsw.gov.au/POWH/researchsupport/default.asp

30 November 2015

A/Prof Danny Eckert
Attention: Mr Benjamin Tong
Neuroscience Research Australia
PO Box 1165
RANDWICK NSW 2031

Dear A/Prof Eckert

HREC ref no: 15/234 (HREC/15/POWH/449)
Project title: Effects of noradregenic and antimuscarinic agents on upper airway dilator muscle activity during sleep: towards a new targeted approach to treat sleep apnoea

Thank you for submitting the above application for ethical and scientific review. The application was first considered by the South Eastern Sydney Local Health District Human Research Ethics Committee (HREC) at a meeting on 29 September 2015.

I am pleased to advise that ethical approval has been granted for this project to be conducted at the following site/s:

- Neuroscience Research Australia
- Prince of Wales Hospital

The following documentation has been approved:

- Response letter to HREC queries , dated 23 November 2015
- Protocol Version 3 dated 20 November 2015
- NEAF application submission code AU/1/9201214, dated 27 August 2015
- Participant Information Sheet, Version 1, August 2015
- Reboxetine Mesilate Product Information
- Buscopan Forte Product Discription
- Sleep Apnoea Advertisement, not dated

The following document was noted:

- NeuroSleep Seed Funding Outcome, dated 7 August 2015

Prince of Wales Hospital
Community Health Services
Barker Street
Randwick NSW 2031

Conditions of approval

1. This approval is valid for 5 years from the date of this letter.
2. Annual reports must be provided on the anniversary of approval.
3. A final report must be provided at the completion of the project.
4. Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the Committee.
5. The Principal Investigator will immediately report matters which might warrant review of ethical approval, including unforeseen events which might affect the ethical acceptability of the project and any complaints made by study participants.

Optional It is the responsibility of the sponsor or the principal (or co-ordinating) investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trials Registry www.anzctr.org.au).

For NSW Public Health sites only: You are reminded that this letter constitutes ethical approval only. You must not commence this research project until you have submitted your Site Specific Assessment (SSA) to the Research Governance Officer of the appropriate institution and have received a letter of authorisation from the General Manager or Chief Executive of that institution.

Should you have any queries, please contact the Research Support Office on (02) 9382 3587. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Research Support Office website: http://www.seslhd.health.nsw.gov.au/POWH/researchsupport/default.asp.

Please quote **15/234** in all correspondence.

We wish you every success in your research.

Yours sincerely

Deborah Adrian

Deborah Adrian
Executive Officer, Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*, NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.