Health
South Eastern Sydney
Local Health District

HUMAN RESEARCH ETHICS COMMITTEE
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RANDWICK NSW 2031
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20 June 2017

Associate Professor Danny Eckert
Neuroscience Research Australia
RANDWICK NSW 2031

Dear A/Prof Danny Eckert

HREC ref no: 16/355 (HREC/16/POWH/710)
Project title: Physiological effects of "z-drugs" in people with obstructive sleep apnoea: Dose response, proof-of-concept studies

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 **17 January 2017.**
Your recent correspondence was reviewed at the HREC Executive Committee meeting on **20 June 2017**
I am pleased to advise that that the proposal meets the requirements of the National Statement on Ethical Conduct of Human Research.

Ethics approval is granted for the following site(s):

- Neuroscience Research Australia
- Prince of Wales Hospital

Ethics approval is granted for the following documents:

- NEAF submission code AU/1/126A24, dated 24 November 2016
- Response Letter, emailed 04 June 2017
- Protocol Version 2 dated May 2017 (clean and tracked changes)
- Participant Information Sheet & Consent Form - The Effects of "Z Drugs" in People With Obstructive Sleep Apnoea Version 2 (Part A - Zopiclone), dated May 2017
- Participant Information Sheet & Consent Form - The Effects of "Z Drugs" in People With Obstructive Sleep Apnoea Version 2 (Part B - Zolpidem), dated May 2017
- Zopiclone Product Information Sheet, dated 12 October 2015
- Zolpidem Product Information Sheet, dated 21 May 2014
- Study advertisement, not dated

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 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 **16/355** in all correspondence.

We wish you every success in your research.

Yours sincerely

Andrew Bohlken
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*.