Health
South Eastern Sydney
Local Health District

HUMAN RESEARCH ETHICS COMMITTEE
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13 February 2017 (updated 28/02/2017)

A/Prof Danny Eckert
Neuroscience Research Australia (NeuRA)
PO Box 1165
RANDWICK NSW 2031

Dear A/Prof Eckert

HREC ref no: 16/356 (HREC/16/POWH/711)
Project title: Targeted combination therapy: Physiological mechanistic studies to inform treatment for obstructive sleep apnoea (OSA).

Thank you for submitting the above application for ethical and scientific review and for your correspondence dated **03 February2017** to the Executive Officer responding to questions which arose at the Executive Committee meeting on **24 January 2017.** Authority to grant final approval was delegated to the Executive Officer. I am pleased to advise that that the proposal meets the requirements of the National Statement on Ethical Conduct of Human Research and ethics approval has been given for the following:

- NEAF Submission AU/1/286A218 dated 25 Nov 2016
- MAS combo Protocol v2 dated Jan 2017
- MAS Combo PIS&CF (Substudy A) v3.1 dated Feb 2017
- MAS Combo PIS&CF (Substudy B) v3.1 dated Feb 2017
- MAS combo Sleep Apnoea Advertisement dated 2016
- NeuRA -Epworth Sleepiness Scale v1 dated Jan 2017

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

- Neuroscience Research Australia (NeuRA)
- Prince of Wales Hospital

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.

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Community Health Services
Barker Street
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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.

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: You are reminded that this letter constitutes ethics 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 **16/356** 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*.