



**HUMAN RESEARCH ETHICS COMMITTEE**

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30 January 2019

A/Prof Matthew Simunovic  
Sydney Eye Hospital  
8 Macquarie Street  
SYDNEY NSW 2000

Dear A/Prof Simunovic

**HREC ref no: 17/092 (HREC/18/POWH/562)**  
**Project title: Two Step versus One-Step Sub-retinal injection**

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 **27 November 2018**. Your recent correspondence was reviewed at the HREC Executive Committee meeting on **25 January 2019**.

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 documents:

- NEAF submission code, AU/1/58A8317 dated 19 August 2018
- Protocol V2.0 dated 11 December 2018
- PISCF V2.0 dated 20 December 2018

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

- Sydney Eye 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.
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](http://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:  
<https://www.seslhd.health.nsw.gov.au/services-clinics/directory/seslhd-research>

Please quote **17/092** 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*.