

Metro North Hospital and Health Service

Royal Brisbane & Women's Hospital Human Research Ethics Committee

| Enquiries to: | Ann-Maree Gordon Coordinator |
|---------------|---------------------------------|
| Telephone: | 07 3646 5490 |
| File Ref: | LNR/2018/QRBW/43509 |
| Email: | RBWH-Ethics@health.qld.gov.au |

Prof Andre van Zundert Anaesthesia and Perioperative Medicine Royal Brisbane & Women's Hospital Herston Qld 4029

Dear Professor van Zundert,

Re: Ref Nº: LNR/2018/QRBW/43509: Patient risks associated with blue and green ambient light in modern interventional suites - an anaesthesic perspective

Thank you for submitting the above research project for single ethical review. This project was received by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (EC00172) on 29 October 2018 and was reviewed by a sub-Committee of the HREC. The research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*.

I am pleased to advise that the sub-Committee has approved of this low risk research project. This approval will be noted by the RBWH Human Research Ethics Committee at its meeting to be held on 10 December 2018.

The nominated participating site for this project is:

• Royal Brisbane & Women's Hospital

This letter constitutes ethical approval only. This project cannot proceed until separate research governance authorisation has been obtained from the CEO or Delegate of the Royal Brisbane & Women's Hospital under whose auspices the research will be conducted.

The approved documents include:

| Document | Version | Date |
|--------------|-----------|-----------------|
| Cover Letter | | 25 October 2018 |
| LNR Form | Oct ver 1 | 25 October 2018 |

Telephone +61 7 3646 5490 www.health.qld.gov.au/metronorth/research/ ethics-governance/default.asp

| Document | Version | Date |
|--|---------|------------------|
| Study Protocol | 1 | 25 October 2018 |
| Data Collection Form 1: Ambient Blue Green Light Study | 1 | 25 October 2018 |
| Data Collection Form 2: Ambient Blue Green Light Study | | 25 October 2018 |
| Curriculum Vitae of Prof Andre van Zundert | | |
| Response to request for further information | | 29 November 2018 |
| Response to request for further information | | 05 December 2018 |
| Participant Information Sheet & Consent Form | 3 | 05 December 2018 |

Approval of this project from the RBWH HREC is valid from **10.12.2018** to **10.12.2021** subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RBWH HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.asp.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the RBWH HREC policy and procedures. These instructions can be found at https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp.
- In accordance with Section 3.3.22 (b) of the National Statement the Coordinating Principal Investigator will report to the RBWH HREC annually in the specified format, the first report being due on **10.12.2019** and a final report is to be submitted on completion of the study. These instructions can be found at https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp.
- The Coordinating Principal Investigator will notify the RBWH HREC if the project is discontinued before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the RBWH HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.asp.

- The Coordinating Principal Investigator will notify the RBWH HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- A copy of this ethical approval letter together with completed Site Specific Assessment (SSA) and any other requirements must be submitted by the Coordinating Principal Investigator to the Research Governance Office at the Royal Brisbane & Women's Hospital in a timely manner to enable the institution to authorise the commencement of the project at its site.
- Should you have any queries about the RBWH HREC's consideration of your project please contact the HREC Coordinator on 07 3646 5490. The RBWH HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/membership/default.asp.

The RBWH HREC wishes you every success in your research.

Yours sincerely,

Gordon B. J.U. Gurk

Dr Gordon McGurk Chairperson RBWH Human Research Ethics Committee Metro North Hospital and Health Service 10.12.2018

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)*. The processes used by this HREC to review research proposals have been certified by the National Health and Medical Research Council.