

Secretary, Human Research Ethics Committee  
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Prof Brian Maguire and  
Mr Nathan Puckeridge  
School of Medical and Applied Sciences  
Rockhampton Campus

26 July 2016

Dear Prof Maguire and Mr Puckeridge

**HUMAN RESEARCH ETHICS COMMITTEE ETHICAL APPROVAL PROJECT: H16/07-200  
KETAMINE IN ACUTE BEHAVIOURAL DISTURBANCE(KIA): THE SAFETY AND  
EFFECTIVENESS OF KETAMINE FOR SEDATION OF PATIENTS WITH ACUTE  
BEHAVIOURAL DISTURBANCE DURING AEROMEDICAL RETRIEVAL**

The Human Research Ethics Committee is an approved institutional ethics committee constituted in accord with guidelines formulated by the National Health and Medical Research Council (NHMRC) and governed by policies and procedures consistent with principles as contained in publications such as the joint Universities Australia and NHMRC *Australian Code for the Responsible Conduct of Research*. This is available at [http://www.nhmrc.gov.au/publications/synopses/\\_files/r39.pdf](http://www.nhmrc.gov.au/publications/synopses/_files/r39.pdf).

On 18 July 2016, the Chair of the Human Research Ethics Committee considered your application under the Low Risk Review Process. This letter confirms that your project has been granted approval under this process, pending ratification by the full committee at its August 2016 meeting.

The period of ethics approval will be from 18 July 2016 to 30 December 2016. The approval number is H16/07-200; please quote this number in all dealings with the Committee. HREC wishes you well with the undertaking of the project and looks forward to receiving the final report.

The standard conditions of approval for this research project are that:

- (a) you conduct the research project strictly in accordance with the proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee;
- (b) you advise the Human Research Ethics Committee (email [ethics@cqu.edu.au](mailto:ethics@cqu.edu.au)) immediately if any complaints are made, or expressions of concern are raised, or any other issue in relation to the project which may warrant review of ethics approval of the project. *(A written report detailing the adverse occurrence or unforeseen event must be submitted to the Committee Chair within one working day after the event.)*
- (c) you make submission to the Human Research Ethics Committee for approval of any proposed variations or modifications to the approved project before making any such changes;
- (d) you provide the Human Research Ethics Committee with a written "Annual Report" on each anniversary date of approval (for projects of greater than 12 months) and "Final Report" by no later than one (1) month after the approval expiry date; *(Forms may be*

downloaded from the Office of Research Moodle site -  
[http://moodle.cqu.edu.au/mod/book/view.php?id=334905&chapterid=17791.](http://moodle.cqu.edu.au/mod/book/view.php?id=334905&chapterid=17791))

- (e) you accept that the Human Research Ethics Committee reserves the right to conduct scheduled or random inspections to confirm that the project is being conducted in accordance to its approval. Inspections may include asking questions of the research team, inspecting all consent documents and records and being guided through any physical experiments associated with the project
- (f) if the research project is discontinued, you advise the Committee in writing within five (5) working days of the discontinuation;
- (g) A copy of the Statement of Findings is provided to the Human Research Ethics Committee when it is forwarded to participants.

Please note that failure to comply with the conditions of approval and the *National Statement on Ethical Conduct in Human Research* may result in withdrawal of approval for the project.

You are required to advise the Secretary in writing within five (5) working days if this project does not proceed for any reason. In the event that you require an extension of ethics approval for this project, please make written application in advance of the end-date of this approval. The research cannot continue beyond the end date of approval unless the Committee has granted an extension of ethics approval. Extensions of approval cannot be granted retrospectively. Should you need an extension but not apply for this before the end-date of the approval then a full new application for approval must be submitted to the Secretary for the Committee to consider.

The Human Research Ethics Committee wishes to support researchers in achieving positive research outcomes. If you have issues where the Human Research Ethics Committee may be of assistance or have any queries in relation to this approval please do not hesitate to contact the Secretary, Sue Evans or myself.

Yours sincerely,



A/Prof Tania Signal  
Chair, Human Research Ethics Committee

Cc: Dr Vinay Gangathimimalah, Dr Minh Le Cong, Dr Luke Burman, Dr Michael Wilson, Dr Kate Hooper,  
Dr Andrew Perry (partner researchers) Project file

**Approved**