



Queensland  
Government

**Metro North**  
Hospital and Health Service

**Royal Brisbane & Women's Hospital  
Human Research Ethics Committee**

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File Ref: HREA/2020/QRBW/63059  
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Prof Kevin Laupland  
Intensive Care Services  
Level 3, Ned Hanlon Building  
Royal Brisbane & Women's Hospital  
Herston Qld 4029

Dear Prof Laupland,

**Re: Ref N<sup>o</sup>: HREC/2020/QRBW/63059: Use of therapeutic drug monitoring (TDM) to optimise oral/enteral hydroxychloroquine dosing in critically ill patients with COVID-19**

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 26 March 2020 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 was ratified by the RBWH Human Research Ethics Committee on 31 March 2020.

A **waiver of consent** has been approved. Please consider permissions under the *Hospital and Health Boards Act 2011* or *Public Health Act 2005* to enable access to confidential information for the purposes of research without consent. If a Public Health Act (PHA) application is applicable, please visit the Health and Medical Research Unit website at: [http://www.health.qld.gov.au/ohmr/html/regu/aces\\_conf\\_hth\\_info.asp](http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp)

Ongoing approval is for the duration of the project, conditional on:

1. In accordance with Section 5.5.6 (b) of the National Statement, the Principal Investigator will report to the HREC annually (**Due by 30 April each year**) in the specified format with a final report to be submitted on completion of the study.

<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>

2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project, in the specified format, including:
  - a. Unforeseen events that might affect continued ethical acceptability of the project.
  - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
3. Amendments to the research project are to be submitted to the HREC for review. Amendments should be reflected in a cover letter from the Principal Investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Further advice on submitting amendments is available from:  
<https://metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting>
4. The Principal Investigator will notify the HREC if the project is discontinued at the participating site(s) with reasons provided.
5. If additional sites are engaged prior to the commencement of, or during the research project, the Principal Investigator is required to notify the HREC. Notification of the withdrawn sites should also be provided to the HREC in a timely fashion accompanying a close out report for that site.

**This letter constitutes ethical approval only.** This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

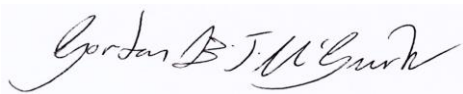
The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Cover Letter		24 March 2020
HREA	Mar ver 1	26 March 2020
Protocol	1.0	24 March 2020
Case Report Form	1.0	23 March 2020
Curriculum Vitae of Kevin B Laupland	February 2020	

**The nominated participating site for this project is:**

- Royal Brisbane & Women's Hospital

Yours sincerely,



Dr Gordon McGurk  
**Chairperson RBWH Human Research Ethics Committee**  
**Metro North Hospital and Health Service**  
31 March 2020

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 multi-centre research proposals have been certified by the National Health and Medical Research Council.