



Queensland  
Government

Metro North  
Hospital and Health Service

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

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File Ref: HREC/2020/QRBW/64090  
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Dr Jayesh Dhanani  
Intensive Care Services  
Level 3, Ned Hanlon Building  
Royal Brisbane & Women's Hospital  
Herston Qld 4029

Dear Dr Dhanani,

**Re: Ref N<sup>o</sup>: HREC/2020/QRBW/64090: The PISA STUDY A comparative study of plasma pharmacokinetics of intravenous and nebulized sedatives and analgesic agents in mechanically ventilated patients: a single centre, prospective observational study**

Thank you for submitting the above research project for single ethical review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) at its meeting held on 08 June 2020.

I am pleased to advise that this research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)* and that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

***Please Note: QCAT should be contacted to seek approval for this clinical research study. QCAT approval will be required prior to submission to the Research Governance Office to obtain authorisation to commence the research study.***

**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		07 April 2020
Telephone Script	1	09 April 2020
Approval from the Department of Intensive Care Services Research Steering Meeting		27 April 2020
Publication in African Journal of Emergency Medicine: <i>Efficacy of nebulized fentanyl and low dose ketamine for pain control of patients with long bone fractures: A randomized, double-blind, clinical trial</i>		

<i>Document</i>	<i>Version</i>	<i>Date</i>
Publication in British Journal of Anaesthesia: <i>Comparison of nebulized dexmedetomidine, ketamine, or midazolam for premedication in preschool children undergoing bone marrow biopsy</i>		
Publication in The American Physiological Society: <i>Effect of clonidine on induced cough and bronchoconstriction in guinea pigs and healthy humans</i>		
Publication in BMC: <i>Nebulized versus intravenous morphine titration for the initial treatment of severe acute pain in the emergency department: study protocol for a multicenter, prospective randomized and controlled trial, CLIN-AEROMORPH</i>		
Publication in Society for Pediatric Anesthesia: <i>A Comparative Evaluation of Nebulized Dexmedetomidine, Nebulized Ketamine, and Their Combination as Premedication for Outpatient Pediatric Dental Surgery</i>		
Publication in Revista Brasileira De Anestesiologia: <i>Preemptive nebulized ketamine for pain control after tonsillectomy in children: randomized controlled trial</i>		
Curriculum Vitae of Dr Jayesh Dhanani		21 October 2018
Curriculum Vitae of Prof Jason Roberts		24 June 2019
Curriculum Vitae of Prof Michael Charles Reade		14 April 2020
Curriculum Vitae of Dr Jason Mark Pincus		
Curriculum Vitae of Melissa May Lassig-Smith		08 April 2020
Curriculum Vitae of Cheryl Fourie		26 September 2019
Response to request for further information		08 June 2020
HREA	Jun ver 2	08 June 2020
Protocol	1.1	05 June 2020
Participant Information Sheet & Consent Form	1.1	05 June 2020
Participant Information Sheet & Consent Form – Person Responsible	1.1	05 June 2020

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.

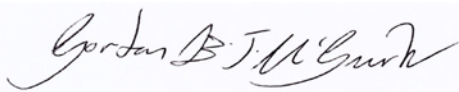
3. Amendments to the research project are to be submitted to the HREC for review. Amendments should be reflected in a cover letter from the Principal Investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Further 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.
- **Please advise the HREC of the date you commence the research project for the approved site(s) using the Notification of Commencement Form:**  
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
  - The 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 nominated participating site for this project is:**

- Royal Brisbane & Women's Hospital

The Royal Brisbane & Women's Hospital Human Research Ethics Committee wishes you every success in your research.

Yours sincerely,



Dr Gordon McGurk  
**Chairperson RBWH** Human Research Ethics Committee  
Metro North Hospital and Health Service  
10 June 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.