Enquiries to: Metro South
Human Research Ethics Committee
Phone: 07 3443 8049
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HREC Ref: HREC/16/QPAH/287
E-mail: EthicsResearch.PAH@health.qld.gov.au

Dr Colin Page
Department of Emergency Medicine
Princess Alexandra Hospital
Woolloongabba Q 4102

Dear Colin

HREC Reference number: HREC/16/QPAH/287
Protocol title: An audit of a change in clinical practice for Queensland Ambulance Service from midazolam to droperidol for prehospital acute behavioural disturbance

Thank you for submitting the above research protocol to the Metro South Health Human Research Ethics Committee for ethical and scientific review. This protocol was considered by the Low Risk Review Panel and will be ratified at the next Metro South HREC meeting.

I am pleased to advise that the Low Risk Review Panel of the HREC has granted a waiver of consent and approved this Quality Assurance monitoring activity to conduct an audit of the change of practice of patients with ABD. This approval relates only to the audit and not in any way to the QAS decision to change its drug management of ABD from Midazolam to Droperidol.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until approval under the Public Health Act 2005 has been granted for the release of confidential information. In addition, appropriate Governance Authorisation needs to be secured from the QAS.

The documents reviewed and approved include:

Document	Version	Date
Low or Negligible Risk Research Application for Ethical Review		14.4.16
Protocol	3	21.4.16
ABD Audit Form	1	13.4.16
CV – Dr Colin Page	1	April 2016
Drug Therapy Protocol – Midazolam		October 2015
Drug Therapy Protocol – Droperidol	1	13.4.16
Copy of Droperidol safety study published September 2015		

This HREC approval is valid from 29/04/2016 until 29/04/2019

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol. Serious Adverse Events must be notified to the HREC as soon as possible. In addition the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of the event.
2. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review. Major amendments should be reflected in a revised online

NEAF (accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents, with *tracked changes*, must also be submitted to the HREC office as per standard HREC SOP.

3. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
4. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
5. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically (track changes) and in hard copy (final clean copy) to the HREC Coordinator. These should include a cover letter from the Principal Investigator or Study Co-ordinator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
6. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
7. The Coordinating Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
8. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.
9. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

Should you have any queries about the HREC's consideration of your protocol please contact Ethics Secretariat on 07 3443 8049.

Please note that the Metro South 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*. Attached is the HREC Composition with specialty and affiliation with the Hospital (Attachment I).

Once authorisation to conduct the research has been granted, please complete the Commencement Form (Attached) and return to the Metro South Human Research Ethics Committee.

The Metro South HREC wishes you every success in your research.

Yours sincerely,

Scott Campbell

A/Prof Scott Campbell
Chair - Low Risk Review Panel
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Centres for Health Research
Princess Alexandra Hospital

29 / 4 / 16