



Royal Brisbane and Women's Hospital
Metro North Health Service District



Queensland
Government

Office of the Human Research Ethics Committees

Queensland Health

Enquiries to: Odette Petersen Coordinator
Phone: 07 3636 5490
Fax: 07 3636 5849
Our Ref: HREC/09/QRBW/262
E-mail: RBWH-Ethics@health.qld.gov.au

Dr Judith Bellapart
Department of Intensive Care Medicine
Level 3, Ned Hanlon Building
Royal Brisbane & Women's Hospital
Herston Q 4029

Dear Dr Bellapart,

Re: Ref N^o: HREC/09/QRBW/262: Exogenous Melatonin in Critically Ill Patients: The Impact On Sleep and ICU Psychosis

Thank you for submitting the above project for ethical and scientific review. This project was considered at the Royal Brisbane & Women's Hospital Human Research Ethics Committee (HREC) meeting held on 21 September, 2009.

I am pleased to advise that the Human Research Ethics Committee has granted approval of this research project on 16 December, 2009. HREC approval is valid for three (3) years from the date of this letter.

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)*, *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 1*).

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the District CEO or Delegate of that site has been obtained.

A copy of this approval will also be sent to the District Research Governance Office (RGO). Please ensure you submit a completed Site Specific Assessment (SSA) Form to the RGO for authorisation from the CEO or Delegate to conduct this research at the Royal Brisbane & Women's Hospital Metro North District.

The documents reviewed and approved include:

The Royal Brisbane & Women's Hospital Human Research Ethics Committee is constituted and operates according to the NHMRC's National Statement on Ethical Conduct in Human Research (2007).

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<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		24 August 2009
Application: NEAF	2.0	23 June 2009
Protocol	2	02 October 2009
Research Funding Schedule (<i>reviewed in accordance with Section 3.3.18 of the National Statement</i>)		
CTN Form (<i>requiring District approval</i>)		
Curriculum Vitae of Michael Graeme Brown		25 August 2010
Ramsay Sedation Scale		
Richmond Agitation Sedation Scale (RASS)		
CAM-ICU Worksheet		
Linking Sedation and Delirium Monitoring: A Two Step Approach to Assess Consciousness		
Response to Request for Further Information		19 November 2009
Response to Request for Further Information		25 November 2009
Response to Request for Further Information		15 December 2009
Substitute Decision Maker Information Sheet & Consent Form	3	25 November 2009
Patient Information Sheet & Consent Form	3	25 November 2009

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - Unforeseen events that might affect continued ethical acceptability of the project. Serious Adverse Events must be notified to the Committee 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 event.
2. Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the HREC Coordinator. These should include a covering letter from the Principal Investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
3. Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research

Governance Office.

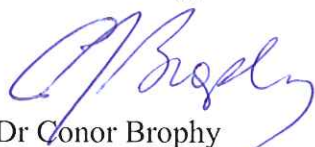
4. Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office (by-passing the HREC).
5. Amendments to the research project which may affect the ongoing ethical acceptability of a project 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 covering 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 Coordinator as per standard HREC SOP. Further advice on submitting amendments is available from http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf
6. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
7. The Principal Investigator will provide an Annual Report to the HREC and at completion of the study in the specified format.
8. The District Administration and the Human Research Ethics Committee may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on Hospital premises or claiming any association with the Hospital, or which the Committee has approved if conducted outside Royal Brisbane & Women's Hospital Metro North Health Service District.

Should you have any queries about the HREC's consideration of your project please contact the HREC Coordinator on 07 3636 5490. The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Once authorisation to conduct the research has been granted, please complete the Commencement Form (*Attachment II*) and return to the office of the Human Research Ethics Committee.

The HREC wishes you every success in your research.

Yours sincerely,



Dr Conor Brophy
Chairperson RBWH Human Research Ethics Committee
Metro North **DISTRICT**
16/12/2009