

30<sup>th</sup> August 2016

Prof Damon Eisen  
Director of Clinical Research  
The Townsville Hospital

[Damon.Eisen@health.qld.gov.au](mailto:Damon.Eisen@health.qld.gov.au)

Dear Prof Eisen,

**HREC reference number: HREC/16/QTHS/160**  
**Project title:** Mechanisms of Aspirin Therapy in Sepsis (MATHS) Trial

Thank you for submitting the above project for ethical and scientific review. This project was considered by Townsville Hospital and Health Service Human Research Ethics Committee (HREC) on 14 August 2015.

The Townsville Hospital and Health Service HREC is constituted according to the National Health and Medical Research Council's '*National Statement on Ethical Conduct in Human Research*' (NHMRC, 2007). The Townsville Hospital and Health Service HREC operates in accordance with the '*Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*' (NHMRC, 2003); and the '*National Statement on Ethical Conduct in Human Research*' (NHMRC, 2007). Attached is the HREC Composition with specialty and affiliation with the Hospital (Attachment I).

The Human Research Ethics Committee has granted approval of this research project. The research proposal meets the requirements of the '*National Statement on Ethical Conduct in Human Research 2007 (updated May 2015)*'. The documents reviewed and approved include:

Document	Version	Date
Response letter		22.08.16
Participant Information Sheet and Consent Form (Person responsible)	2.0	18.08.16
Participant Information Sheet and Consent Form (Self)	2.0	18.08.16
NEAF Application Form (AU/1/9C9728)		21.07.16
Study Protocol	1.0	11.07.16
Form for Withdrawal of Participation (Person responsible)	1.0	13.07.16
Form for Withdrawal of Participation (Self)	1.0	13.07.16
Appendix 1 – Study data fields		
Curriculum Vitae – E.Heyer		
Melbourne Health HREC approval		08.08.11
NHMRC Assessment Report – APP1009217		19.07.10

The research project has ethical approval for the following sites:  
The Townsville Hospital

Please note the following key dates for this study:

**HREC approval expiry: 29/08/2024**

**Annual report due: 29/08/2017**

**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 Health Service CEO or Delegate of that site has been obtained.**

**A copy of this approval must be submitted to the Health Service Research Governance Officer/Delegated Personnel with a completed Site Specific Assessment (SSA) Form and supporting study documents for authorisation from the CEO or Delegate to conduct this research at the approved sites. Refer to the local THHS website for further information on Site**

**Specific Assessment:** <http://qheps.health.qld.gov.au/tville/district-executive/medical-services/mssu-ethics.htm>

Please note the following conditions of approval:

The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

- Unforeseen events: please notify the HREC if any occur 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.

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 application form (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 application form, 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/html/regu/regu\\_home.asp](http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp)

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/r (by-passing the HREC).

Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly the HREC for review and, once HREC approval has been granted, then submitted to the RGO.

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 cover 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.

The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format. The final report should include a copy of the results and/or publication, if not available at the time of reporting these must be provided in a timely manner.

The Health Service 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 the approved sites.

Should you have any queries about the HREC's consideration of your project please contact me on (07) 4433 1440. 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](http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp)

The HREC wishes you every success in your research.

Kind regards



**Dr Nikola Stepanov**  
**Chairman**  
**Townsville Hospital and Health Service**  
**Human Research Ethics Committee**