



Queensland
Government

Metro North
Hospital and Health Service

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

Enquiries to: Ann-Maree Gordon
Coordinator
Telephone: 07 3646 5490
File Ref: LNR/2019/QRBW/48376
Email: RBWH-Ethics@health.qld.gov.au

Dr Alexis Tabah
Intensive Care Unit
Redcliffe Hospital
Anzac Avenue
Redcliffe Qld 4020

Dear Dr Tabah,

Re: Ref №: LNR/2019/QRBW/48376: EUROBACT 2 - Epidemiology and determinants of outcomes of Hospital Acquired Blood Stream Infections in the Intensive Care.

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 25 January 2019 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 22 February 2019.

The waiver of consent and breach of the Australian Privacy Principles were considered justified in accordance with National Statement 2.3.10 and are 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

The nominated participating sites for this project are:

- Royal Brisbane & Women's Hospital
- The Prince Charles Hospital
- Redcliffe Hospital
- Caboolture Hospital

Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the RBWH HREC. Notification of withdrawn sites should also be provided to the RBWH HREC in a timely fashion.

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		25 January 2019
HREA	Jan ver 1	25 January 2019
Eurobact II Study Protocol	1.02	11 January 2019
Eurobact II Centre Case Report Form	1.0	11 January 2019
Eurobact II Case Report Form	1.02	21 January 2019
Antibiogram Tables	1.0	11 January 2019
Letter of support from the ESCMID Study Group for Infections in Critically Ill Patients for the application for study group research funding		14 June 2018
Letter of support from the ESICM Trials Group on behalf of the ESICM Research Committee		18 September 2018
Curriculum Vitae of Alexis Tabah		18 January 2019
Curriculum Vitae of Dr Mahesh Ramanan		19 January 2019
Response to request for further information		19 February 2019

Approval of this project from the RBWH HREC is valid from **22.02.2019** to **22.02.2022** subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RBWH HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.asp>.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the RBWH HREC policy and procedures. These instructions can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>.
- In accordance with Section 3.3.22 (b) of the National Statement the Coordinating Principal Investigator will report to the RBWH HREC annually in the specified format, the first report being

due on **22.02.2020** and a final report is to be submitted on completion of the study. These instructions can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>.

- The Coordinating Principal Investigator will notify the RBWH HREC if the project is discontinued before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the RBWH HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.asp>.
- The Coordinating Principal Investigator will notify the RBWH HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- A copy of this ethical approval letter together with completed Site Specific Assessment (SSA) and any other requirements must be submitted by all site Principal Investigators to the Research Governance Office at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.
- Should you have any queries about the RBWH HREC's consideration of your project please contact the [HREC Coordinator on 07 3646 5490](mailto:rbwh.hrec@health.qld.gov.au). The RBWH 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 RBWH HREC wishes you every success in your research.

Yours sincerely,



Dr Gordon McGurk
Chairperson RBWH Human Research Ethics Committee
Metro North Hospital and Health Service
22.02.2019

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