ERM Filter Questions

In which jurisdiction will your ethics application be submitted for review?

- (•) Queensland Health
- ( ) Victoria
- ( ) Mater

Project Title *CHANGES TO THIS FIELD WILL UPDATE THE TITLE FOR THE ENTIRE PROJECT*

EUROBACT 2 - Epidemiology and determinants of outcomes of Hospital Acquired Blood Stream Infections in the Intensive Care.

Is **this ethics application** single-site or multi-site?

Single-site = one health service (including multiple campuses within that health service or institution).
Multi-site = more than one health service or institution.

- ( ) Single-site
- (•) Multi-site

Coordinating Principal Investigator

Title

Doctor

First Name

Alexis

Surname

Tabah

Organisation

Redcliffe Hospital

Department

Intensive Care Unit

Address

The Redcliffe Hospital

Anzac Avenue

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State

Queensland

Postcode

4020

Country

Australia

Telephone

0432 500 609

Email

alexis@tabah.org

Is the Coordinating Principal Investigator the contact person for this application?

- ○ Yes
- ◉ No

Contact person for this application

Title

Ms

First Name

Cheryl

Surname

Fourie

Telephone

07 3646 8894

Email

cheryl.fourie@health.qld.gov.au

Have you shared this form with colleagues at each site?

- [x] Yes

Will this ethics application involve a site in Victoria?

- ( ) Yes
- (•) No

Provide details of all sites/organisations included **in this ethics application**

State/Territory

Queensland

Name of site/organisation

Royal Brisbane and Women's Hospital

Provide details of all sites/organisations included **in this ethics application**

State/Territory

Queensland

Name of site/organisation

Redcliffe Hospital

Provide details of all sites/organisations included **in this ethics application**

State/Territory

Queensland

Name of site/organisation

Caboolture Hospital

Provide details of all sites/organisations included **in this ethics application**

State/Territory

Queensland

Name of site/organisation

The Prince Charles Hospital

Major sponsor type

Collaborative group

Australian sponsor name

Dr Alexis Tabah

Sponsor contact (Australia)

Title

Dr

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Study type

Clinical research

Protocol number

Version 01.02

Participant cohort(s) Tick all that apply

- [x] Adults
- [ ] Children and young people

NHMRC Fields of Research - Research category

INTENSIVE CARE

Local reference number Optional

Select the committee that your ethics application will be submitted to.

Royal Brisbane and Women's Hospital - Royal Brisbane & Women's Hospital Human Research Ethics Committee

Human Research Ethics Application

Section 1 - Core Information

Pre-application conditions

Before completing this application, acknowledge that:

1) The HREA has been designed for ethics review of human research, as defined in the National Statement. *

2) Adequate resources must be available to conduct this research project. *

3) All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to. *

4) Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided. *

◉ Acknowledge and Continue

HREC Directory

HREC Directory

HRECs that are willing to accept the HREA are listed in Q4.3. If your HREC is not listed it may not be accepting the HREA from this website and you will be unable to complete this application.

You may wish to seek advice from a HREC while completing your application. Click here for HREC contact information.

Project Overview

Q1.1 What is the Project Title (as presented in the Project Description/Protocol)? *

Epidemiology and determinants of outcomes of Hospital Acquired Blood Stream Infections in the Intensive Care. (Eurobact II)

Q1.2 Provide a summary of the research project in non-technical language. *

Sepsis is recognised as one of the leading causes of mortality and has become healthcare priority in Australia and worldwide. Blood stream infection (BSI) is the perfect model of infection to study the effects of the micro-organism on the patient, and the effects of the antibiotics and other treatments on survival. The Eurobact 1 study collected multinational data on Hospital-acquired blood stream infection (HA-BSI) in 2010-11. It has been topical in describing the relationship between antimicrobial resistance (AMR) and increased delays in effective drug therapy and how resistance is independently associated with mortality.

Eurobact II is a multinational, multicentre observational study of critically ill patients focusing on HA-BSI with in the intensive care unit with the following objectives:

To:
• describe the epidemiology and determinants of management and outcome of HA-BSI treated in the ICU
• describe epidemiological changes since the Eurobact 1 study.

Inclusion criteria:
All adult patients with a HA-BSI treated in the ICU.
During a 3-consecutive month period or 10 consecutive HA-BSI per ICU whichever comes first.

Q1.3 Which category/ies of research best describes the project? *

Intensive Care Medicine
Sepsis - Blood Stream Infections

Q1.4 In what environment/s will the research be conducted? *

- ☐ Clinic(s)
- ☐ Community centre(s)
- ☐ Cultural/religious organisation(s)
- ☑ Hospital(s)
- ☐ Online
- ☐ Private residence(s)
- ☐ Professional organisation(s)
- ☐ Public place(s)
- ☐ Research institute(s)
- ☐ School system(s)
- ☐ University(ies)
- ☐ Workplace(s)
- ☐ Other

Q1.5 What organisation/entity has overall responsibility for this project? *

European Society of Intensive Care Medicine (ESICM)

Q1.6 Describe how this research project is currently, or will be, funded. *

A grant of 25 000 euros has been awarded by the ESICM Trials Group for operational management of the study and eCRF management.

An AU$5000 grant has been awarded by the Norva Dahlia foundation specifically to facilitate patient inclusions in Australia.

Q1.7 When do you anticipate starting the research project? *

- [x] As soon as ethics and any other relevant approvals have been provided.
- [ ] I have a start date

Q1.8 What is the anticipated duration of the research project? *

2 Years

Team Member Details

Project Team

Q1.9.1 Title

Dr

Q1.9.2 First Name

Alexis

Q1.9.3 Surname/family name

Tabah

Q1.9.4 Email Address

alexis@tabah.org

Q1.9.5 Is this person the contact person for this application?

- ○ Yes
- ◉ No

Q1.9.6 Is this person a student on this project?

- ○ Yes
- ◉ No

Q1.9.7 Institutional affiliation and position.

MD, FCICM
Intensive Care Specialist - Redcliffe and Caboolture Hospitals
International Primary Investigator for Eurobact II (ESICM)

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

CHIEF INVESTIGATOR/RESEARCHER

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

- ◉ Yes
- ○ No

Q1.9.12 Describe the research activities this person will be responsible for.

Dr Tabah is responsible for the overall conduct of the study at an international level.
As a National Coordinator he is responsible for the oversight of all Australian sites
As the Principal Investigator for Redcliffe and Caboolture Hospitals, he will be responsible for overseeing the conduct of the study at the site, including but not limited to appropriate participant recruitment, and data collection quality

Q1.9.13 Describe the person's expertise relevant to the research activity.

Staff specialist in Intensive Care Medicine with extensive experience in clinical trials and research.

Project Team

Q1.9.1 Title

Professor

Q1.9.2 First Name

Jeffrey

Q1.9.3 Surname/family name

Lipman

Q1.9.4 Email Address

j.lipman@uq.edu.au

Q1.9.5 Is this person the contact person for this application?

- ○ Yes
- ◉ No

Q1.9.6 Is this person a student on this project?

- ○ Yes
- ◉ No

Q1.9.7 Institutional affiliation and position.

MBBCh, DA, FFA (Crit Care), FCICM, MD
Intensive Care Specialist Royal Brisbane and Women's Hospital
Principal Investigator for Royal Brisbane & Women's Hospital

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

PRINCIPAL INVESTIGATOR

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

- ○ Yes
- ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

The Investigator will be responsible for overseeing conduct of the study at the site including appropriate participant recruitment and quality of data

Q1.9.13 Describe the person's expertise relevant to the research activity.

Staff specialist in Intensive Care Medicine with extensive experience in clinical trials and research, particularly sepsis and infection research.

Project Team

Q1.9.1 Title

Dr

Q1.9.2 First Name

Mahesh

Q1.9.3 Surname/family name

Ramanan

Q1.9.4 Email Address

mahesh.ramanan@health.qld.gov.au

Q1.9.5 Is this person the contact person for this application?

- ○ Yes
- ◉ No

Q1.9.6 Is this person a student on this project?

- ○ Yes
- ◉ No

Q1.9.7 Institutional affiliation and position.

BSc(Med) MBBS MMed (Clin Epi) FCICM
Intensive Care Specialist The Prince Charles and Redcliffe Hospitals
Principal Investigator for The Prince Charles Hospital.

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

PRINCIPAL INVESTIGATOR

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

- ○ Yes
- ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

The Investigator will be responsible for overseeing conduct of the study at the site including appropriate participant recruitment and quality of data

Q1.9.13 Describe the person's expertise relevant to the research activity.

Staff specialist in Intensive Care Medicine with previous experience in clinical trials and research.

Project Team

Q1.9.1 Title

Ms

Q1.9.2 First Name

Cheryl

Q1.9.3 Surname/family name

Fourie

Q1.9.4 Email Address

cheryl.fourie@health.qld.gov.au

Q1.9.5 Is this person the contact person for this application?

- ○ Yes
- ○ No

Q1.9.5.1 Contact Email Address

cheryl.fourie@health.qld.gov.au

Q1.9.5.2 Contact Phone number

07 3646 8894

Q1.9.5.3 Contact Mailing address

Department of Intensive Care Medicine, Royal Brisbane and Women's Hospital, Level 3 Ned Hanlon Building, Butterfield Street

City

Herston

State

Qld

Postcode

4029

Country

Australia

Q1.9.6 Is this person a student on this project?

- ○ Yes
- ◉ No

Q1.9.7 Institutional affiliation and position.

Bachelor of Nursing
Clinical Research Coordinator
Department of Intensive Care Medicine
Royal Brisbane and Women's Hospital

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

ASSOCIATE/ASSISTANT/SUB/CO-INVESTIGATOR/RESEARCHER

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

- ○ Yes
- ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

Will participate in patient recruitment, data collection, data integrity,

Q1.9.13 Describe the person's expertise relevant to the research activity.

Bachelor Nursing, Post Grad cert Critical Nursing
Research Coordinator Intensive Care Services
Experience in coordinating numerous clinical trials

Disclosure of Interests

Q1.10 Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research? *

- ○ Yes
- ◉ No

Restrictions

Q1.11 Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project? *

- ○ Yes
- ◉ No

Evaluations

Q1.12 Has the scientific or academic merit of the research project been evaluated? *

- ◉ Yes
- ○ No

Q1.12.1 What was the review process and what was the outcome? *

European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Study Group for Critically Ill Patients - Dated 14 June 2018
Outcome - Grant application for Study Group Research Funding with the European Society of Clinical Microbiology and Infectious Disease
European Society of Intensive Care Medicine (ESICM) Research Committee
Outcome - Eurobact II successfully underwent a review process by the ESICM Research Committee and the ESICM Executive Committee decided to give a favourable answer on 4 July 2018.

Q1.12.2 Attach evidence of the outcome of the scientific or academic review process. Optional

Type	Document Name	File Name	Version Date	Version	Size
Evidence of the outcome	Scientific_Peer_Review_ESCMID_14_June_18	Scientific_Peer_Review_ESCMID_14_June_18.pdf	14/06/2018		124.5 KB

Q1.12.2 Attach evidence of the outcome of the scientific or academic review process. Optional

Type	Document Name	File Name	Version Date	Version	Size
Evidence of the outcome		ESICM Letter of support 18 September 2018.pdf			317.0 KB

Q1.13 Has this research project had prior ethics review? *

- ○ Yes
- ◉ No

Q1.14 Will any further or additional specialised review of this application be sought? *

- ○ Yes
- ◉ No

Location

Q1.15 Will this research project be conducted at multiple sites? *

- ◉ Yes
- ○ No

Q1.16 Will separate institutional approvals or authorisations be required prior to commencing research at each site? *

- ◉ Yes
- ○ No

Section 2 - Research Details and Participants

Methods

Q1.17 From the list below, select all the research methods that will be used in the research project. *

- ☐ Action research
- ☐ Biospecimen analysis research
- ☐ Data linkage research
- ☐ Ethnographic research
- ☐ Epidemiological research
- ☐ Interventional/ Clinical Trial research
- ☑ Observational research
- ☐ Survey/Interview/Focus Group research
- ☐ Textual analysis research
- ☐ None of the above

Participants

Q1.18 Indicate with whom or with what the research will be conducted *

- ○ Human beings (via active participation), including their associated biospecimens and/or data
- ○ Human biospecimens only
- ◉ Data associated with human beings only (i.e. as the primary object of research)

Q1.18.1 Does your research involve the prospective collection of data? *

- ◉ Yes
- ○ No

Q1.19 Will your research involve participation of any of the following? *

- ☐ Women who are pregnant and the human fetus
- ☐ Children and young people
- ☑ People highly dependent on medical care who may be unable to give consent
- ☐ People with a cognitive impairment, intellectual disability or mental illness
- ☐ People in dependent or unequal relationships
- ☐ People who may be involved in illegal activities
- ☐ People in other countries
- ☐ Aboriginal and Torres Strait Islander peoples

Method Specific Questions

You have indicated that the following methods will be involved in your research in 1.17 .

- **Observational research** .

Observational research

M7.1 What type of observation will you be conducting? * .

The study is observational with no interventions. Observation will occur for all adult patients with a Hospital Acquired Bloodstream Infection (HA-BSI) treated in the ICU. Data collection will be from the patients medical record.

M7.2 What sampling strategy will you use? *

All patients under the direct care of the ICU team will be evaluated for study eligibility. The treating team will notify the research team of adult patients with a Hospital Acquired Bloodstream Infection (HA-BSI) and they will be assessed according to inclusion and exclusion criteria. This will occur over 3 consecutive months or 10 consecutive hospital-acquired bacteraemia per intensive care unit, which ever comes first,

M7.3 How will you match and follow up participants? *

Each study participant will be given a unique code number when entered into the study and this will be entered into the database. There will be a document in a paper or electronic format that links the study ID codes to participant names. This document will be kept with all study related documents stored in a secure locked location or password protected files at each site and accessed only by local ICU research staff.

M7.4 How will potential sources of bias be addressed, including consideration of both the direction and magnitude of bias? *

Potential selection bias will me minimised by the treating ICU team considering all patients for suitability and discussing with the research team before including in the study

Participant Specific Questions

You have indicated that the following will be involved in your research:

- **Data associated with human beings only (i.e. as the primary object of research)**

You have indicated that the following participants will or are likely to be involved in your research:

- **People highly dependent on medical care who may be unable to give consent**

People highly dependent on medical care

P3.1 Who will the research involve? *

- ☐ People receiving neonatal intensive care
- ☑ People receiving intensive care
- ☐ People receiving emergency care
- ☐ People receiving end-of-life care
- ☐ People who are unconscious

P3.2 Describe how the research will be minimally invasive or provide a therapeutic benefit that is related to the participants' condition. *

The Eurobact II study is purely observational. It does not introduce any interventional procedure. The data is extracted from the patients' medical records and does not affect local standard of care. Hence, the study does not add any additional risk to the patients recruited.
All data will be de-identified and given unique identifiers to maintain confidentiality of participants.

P3.3 Describe how the research will lead to increased understanding about, or improvements in, the care of people receiving this type of medical care or who are in this condition. *

The patients enrolled in the study will not benefit directly from the research. Eurobact II study will provided granular data and the opportunity to investigate how management and outcomes of patients with severe hospital acquired infections may have changed while there has been a worldwide increase in AMR. The potential benefit of the study consists in improving knowledge for better medical management for similar patients in the future and the generation of hypotheses for further collaborative research.

Recruitment

Consent 1

Q2.2.1 Indicate the relevant section/s of your Project Description/Protocol that address/es consent. *

We are seeking a waiver of consent for this study as per the National Statement section 2.3.10, as it involves collection of routinely collected patient data. The project involves only the analysis of de-identifiable existing datasets. Nil patient identifiers will be recorded or transcribed into the databasefor analysis. The investigators believe it would be unnecessarily burdensome on family members to consent to the participation of their relative in this low risk observational data collection. There is no requirement for any diagnostic test or intervention additional to what the patient is receiving as part of their treatment.
All data will be anonymously collected on a secured webserver by the operational committee. No identifying data will be collected.
(Protocol V 1.02 page 7 - Ethical Considerations)

Q2.2.2 Will you be obtaining consent from some or all participants to participate in the research? *

- ○ Yes for all participants
- ○ Yes for some participants
- ◉ Not for any participants

Consent 2

Q2.2.3 Are family members, authorised representatives or any others involved in the participants' decision to participate in the research? *

- ○ Yes
- ◉ No

Q2.2.P1.P3.1 Will the process of providing information and obtaining consent from the participants be separate from obtaining consent for non-research purposes (such as for a clinical procedure)? *

- ◉ Yes
- ○ No

Q2.2.P1.P3.1.1.1 How will you ensure that these processes are separate? *

As we are seeking a waiver of consent for this study as per the National Statement section 2.3.10,neither the participant or their person responsible will be approached regarding participation.

Q2.2.4 Will there be an opportunity to confirm or re-negotiate consent during the research project? *

- ○ Yes
- ◉ No

Q2.2.6 Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues. *

We are seeking a waiver of consent for this study as per the National Statement section 2.3.10, as it involves collection of routinely collected patient data. The project involves only the analysis of de-identifiable existing datasets. Nil patient identifiers will be recorded or transcribed into the databasefor analysis. The investigators believe it would be unnecessarily burdensome on family members to consent to the participation of their relative in this low risk observational data collection. The data will be de-identified and coded to ensure patient privacy is maintained.

Alternatives to Consent

Q2.2.7 Are you proposing to use an opt-out approach with respect to some or all participants? *

- ○ Yes
- ◉ No

Q2.2.8 Are you requesting a waiver of the requirement for consent with respect to some or all participants? *

- ◉ Yes
- ○ No

Q2.2.8.1 How will you ensure that the research satisfies the guidance for waiving consent as listed in National Statement 2.3.10? *

We are seeking a waiver of consent for this study as per the National Statement section 2.3.10, as it is purely observational and involves collection of routinely collected patient data. The project involves only the analysis of de-identifiable existing datasets. Nil patient identifiers will be recorded or transcribed into the database for analysis. The investigators believe it would be unnecessarily burdensome on family members to consent to the participation of their relative in this low risk observational data collection. The data will be de-identified and coded to ensure patient privacy is maintained.

Consent - Highly dependent on medical care

Q2.2.P3.1 Will some or all of the participants have impaired capacity to provide consent for participation in the research? *

- ◉ Yes
- ○ No

Q2.2.P3.1.1 Are you intending to commence the research without prior consent from the participants or authorised representatives as per National Statement 4.4.13? *

- (•) Yes
- ( ) No

Q2.2.P3.1.2 How will you communicate with and obtain consent from the participants' carers, their families, their guardians and/or other responsible persons? *

As we are seeking a waiver of consent for this study we would not be obtaining consent from participants or their person responsible.

Q2.2.P3.2 Describe how the process of obtaining consent (or not obtaining consent) is consistent with the processes outlined in National Statement 4.4.9-14. *

We are seeking a waiver of consent for this study as per the National Statement section 2.3.10, as it involves collection of routinely collected patient data. The project involves only the analysis of de-identifiable existing datasets. Nil patient identifiers will be recorded or transcribed into the databasefor analysis. The investigators believe it would be unnecessarily burdensome on family members to consent to the participation of their relative in this low risk observational data collection. The data will be de-identified and coded to ensure patient privacy is maintained.

Risk - General

Q2.3.1 Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description/Protocol as appropriate. *

As this study is observational and does not involve any additional interventions or change to practice, and does not involve any patient and/or their substitute decision maker engagement, it is deemed that the patient involvement in this study carries no foreseeable risk. The data is already collected as part of patient care and it will be de-identified prior to being entered into the data base.

Q2.3.2 Describe how these risks will be mitigated and managed. *

All data will be collected and de-identified/coded. The data collected will be stored in a locked office, at each site and accessed only by local ICU research staff. No identifiable data will be transferred to the sponsor. Information entered in the study database will be de-identified and stored securely with restricted access (password protected computers), verifiable audit trails and in compliance with all regulations concerning the electronic storage of data.

Benefit

Q2.4.1 Describe the benefits associated with your research, referencing any relevant sections of your Project Description/Protocol as appropriate. *

The patients enrolled in the study will not benefit directly from the research. The benefits of the Eurobact II study is that it will provided granular data and the opportunity to investigate how management and outcomes of patients with severe hospital acquired infections may have changed while there has been a worldwide increase in AMR. The potential benefit of the study consists in improving knowledge for better medical management for similar patients in the future and the generation of hypotheses for further collaborative research.

Q2.4.2 Explain how the benefits of this research justify any risks or burdens associated with the research. *

As this study is observational and does not involve any patient or substitute decision maker engagement, nor any interventions, it is felt that there is no foreseeable risk to participation. The potential benefit of the study consists in improving knowledge for better understanding and medical management for similar patients in the future and the generation of hypotheses for further collaborative research.

Q2.4.3 How will you manage participants' expectations of the perceived benefit of participating in the research? *

As this is an observational study, this study will not affect participants' medical care or treatment for their current admission. Future patients may benefit from and improved understanding of the prevalence and epidemiology of Hospital Acquired Blood Stream Infections and the potential for improved medical management.

Section 3 - Data and Privacy

Data Characteristics

Q3.1 Indicate the type of information/data you will be collecting for this project. *

- ☐ Personal information
- ☐ Sensitive information
- ☑ Health information
- ☐ Not personal information

Q3.2 Indicate the type of information/data you will be using in this project. *

- ☐ Personal information
- ☐ Sensitive information
- ☑ Health information
- ☐ Not personal information

Q3.3 Indicate the degree of identifiability of information/data you will be collecting for this project. *

- ☐ Individually identifiable information
- ☑ Re-identifiable (coded) information
- ☐ Non-identifiable information

Q3.4 Indicate the degree of identifiability of information/data you will be using in this project. *

- ☐ Individually identifiable information
- ☑ Re-identifiable (coded) information
- ☐ Non-identifiable information

Q3.5 Describe any ethical considerations relating to the collection and/or use of the information/data in this project. *

Once enrolled in the study, subjects will be identified by a unique number specific to this study. This number is re-identifiable only through the enrolment log, which will be kept in a locked and secure location at each site and accessed only by local ICU research staff. Only the study specific identification number will be used in further data analysis. All data will be anonymously collected on a secured webserver by the operational committee. No identifying data will be collected. (Protocol V 1.02 Page 7)

Q3.6 Identify the source/s of the information/data that you will be collecting and/or using in this project. *

- ☐ Individual participants and/or relatives or associates of participants
- ☑ Medical/health/mental health record
- ☐ Electoral roll
- ☐ Held by a law enforcement agency or judicial body
- ☐ Publicly held database (Commonwealth)
- ☐ Publicly held database (State or local)
- ☐ Privately held database

Q3.6.1 Has the data custodian/s, if any, agreed to provide access to the data for use in the proposed research?

- Approval to release data may be granted by a data custodian prior to, or subject to, ethics approval being obtained. If ethics approval is a precondition for applying for data custodian approval, select 'data custodian has not provided approval'.
- If there is no data custodian, select 'no data custodian identified'

- ○ Data custodian has approved access to data
- ◉ Data custodian has not provided approval
- ○ No data custodian identified

Q3.7 Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question. *

All data for the Eurobact II study will be gathered from existing medical records created fro the purpose of general care. All data entered in to the data base will be de-identified. The master list which enables re-identification of the participants will remain at all times in a locked office at each site and accessed only by local ICU research staff. All computer records will be password protected.

Q3.8 Was the information/data that you are using previously collected for a purpose other than research? *

- ◉ Yes
- ○ No

Q3.8.1 Provide a rationale for your use of information/data for a purpose other than that for which it was originally collected. *

The use of data already collected as part of the participants care will provide information on the epidemiology and determinants of the outcome and management of HA-BSI. This granular data on management and outcomes of patients with severe hospital acquired infections will provide invaluable information for future management of HA-BSI.

Activities Planned for/with Data

Q3.9 Do you plan to disclose any personal information/data in this project to a third party? *

- ○ Yes
- ◉ No

Q3.10 How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research. *

The sites will ensure that source data will be stored in a safe environment such as a locked office at each site and accessed only by local ICU research staff. No data identifying the participants will be removed from the site. No identifiable data will be transferred to the sponsor. Information entered in the study database will be de-identified and stored securely with restricted access (password protected computers), verifiable audit trails and in compliance with all regulations concerning the electronic storage of data.

Q3.11 Are there any restrictions on your ability to assure the confidentiality of participants? *

- ○ Yes
- ◉ No

Q3.12 Do you plan to share any individual research results obtained during this research to the participants? *

- ○ Yes
- ◉ No

Q3.13 Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data. *

The data collected for this study will be de-identified using the subject number which will protect the participants' privacy. The research conducted is not expected to investigate information that would be personally relevant to participants.

Q3.14 Describe how the information/data will be stored, accessed, archived and/or destroyed. *

At the end of the study, all study related data and files will be archived for 15 years to comply with Good Clinical Practice (GCP), after this time the information will be destroyed securely.

Q3.15 Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project. *

We do not anticipate any potential ethical concerns relating to this study as storage access and destruction of information/data will be performed according to ICH -GCP guidelines.

Q3.16 Will the outcomes of this project be disseminated to the participants? *

- ○ Yes
- ◉ No

Q3.16.2.1 Justify why the outcomes of this project will not be disseminated to the participants. *

Results of the study will be used to describe worldwide epidemiology and determinants of outcome of HA-BSI. This information may have little relevance at the
individual patient level and will be of little consequence to them.

Q3.17 Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available. *

Non identifiable data collected for this study will be stored in an encrypted database. It will be further transformed and re-coded for data analysis to a working database that will be encrypted and non identifiable. Parts of the working database or of its analysis may potentially be shared with other researchers from the steering committee to investigate HA-BSI and for ancillary analysis.
Any request for analysis will be reviewed by the primary investigators prior to approval.
There is no expectation that this data will need to be made publicly available by the funder or publishers.

Q3.18 Describe any ethical considerations relating to the planned or possible future use of information/data in this project. *

Any data from this project that is used for other research will be non-identifiable.

Section 4 - Attachments and Declarations

Attachments

Q4.1 Attach the Project Description/Protocol to your HREA. *

- It is recommended that you use one of the templates provided in the HREA for your Project Description/Protocol.
- Individual attachments are limited to 10 MB in size.

Type	Document Name	File Name	Version Date	Version	Size
Protocol	Eurobact2-protocol-1.02_11_01_2019	Eurobact2-protocol-1.02_11_01_2019.pdf	11/01/2019	1.02	1,019.8 KB

Q4.2 Are there any other relevant documents associated with conducting your research project?

- (•) Yes
- ( ) No

Attach any other relevant documents associated with conducting your research project. Optional

Select the specific supporting document types to be uploaded.

- ☐ Advertising material
- ☑ Case report form
- ☐ Copy of ethics approval
- ☐ Curriculum vitae (CV) or resume of investigator/researcher
- ☐ Data management plans
- ☐ Drug data sheet
- ☐ Ethically defensible plans
- ☐ Evidence of Clinical Trial Notification (CTN)
- ☐ Form of indemnity
- ☐ GP/consultant information
- ☐ Institutional biosafety committee (IBC) approval
- ☐ Investigator brochure or reference safety information
- ☐ Invitation to participant
- ☐ Letter of support
- ☐ Licence for dealing with a genetically modified organism
- ☐ NSW privacy form
- ☐ Participant documentation e.g. diary, wallet card
- ☐ Participant information and consent form
- ☐ Peer review
- ☐ Protocol (Tracked)
- ☐ Questionnaire
- ☐ Radiation: letter re standard care
- ☐ Radiation: medical physicist's report
- ☐ Report forms
- ☐ Statistician comments
- ☐ Western Australian specific module
- ☐ Other project-related documentation

Case report form

Type	Document Name	File Name	Version Date	Version	Size
Case report form	Eurobact2-center-1.0_11_Jan_2019	Eurobact2-center-1.0_11_Jan_2019.pdf	11/01/2019	1.0	531.5 KB
Case report form	Eurobact2-CRF-1.02_21_01_2019	Eurobact2-CRF-1.02_21_01_2019.pdf	21/01/2019	1.02	1.0 MB
Case report form	Eurobact2-Pathogen-tables-1.0_11_01_2019	Eurobact2-Pathogen-tables-1.0_11_01_2019.pdf	11/01/2019	1.0	496.8 KB

Curriculum vitae

Type	Document Name	File Name	Version Date	Version	Size
Curriculum vitae	CV Alexis Tabah_2019	CV Alexis Tabah_2019.pdf	18/01/2019		271.1 KB
Curriculum vitae	CV Mahesh Ramanan Jan 2019	CV Mahesh Ramanan Jan 2019.pdf	19/01/2019		429.5 KB

HREC

Q4.3 Select the Organisation that hosts the HREC or other review body and (Q4.4) the HREC or other body to which you are applying from the list below *

Royal Brisbane and Women's Hospital - Royal Brisbane & Women's Hospital Human Research Ethics Committee

Q4.5 Under which review pathway are you intending to submit this application? *

Negligible risk review pathway

Q4.6 Will this application be reviewed under the National Mutual Acceptance scheme?

- (•) Yes
- ( ) No

Investigator Team Declarations

Indicate which members must sign this application

- [x] Chief Investigator/Researcher
- [ ] Coordinating Principal Investigator/Researcher
- [ ] Lead Investigator/Researcher
- [x] Principal Investigator
- [x] Associate/Assistant/Sub-/Co-Investigator/Researcher
- [ ] Investigator/Researcher
- [ ] Other

Declaration - CI/CPI/Lead Investigator

Chief Investigator/Researcher

I, (insert name)

Dr Alexis Tabah

certify that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Electronic signature

Declaration - PI

Principal Investigator

I, (insert name)

Professor Jeffrey Lipman

certify that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Sign here: .....

Date: .....

Principal Investigator

I, (insert name)

Dr Mahesh Ramanan

certify that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Sign here: .....

Date: .....

Declaration - AI/Investigator

Associate/Assistant/Sub-/Co-Investigator/Researcher

I, (insert name)

Cheryl Fourie

certify that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Electronic signature

Generate HREA document

Is your application complete and have you attached the Project Description/Protocol and any relevant supporting documents? *

- (•) Yes
- ( ) No

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