ETHICS APPROVAL

21 May 2024

A/Prof Elliot Long
Emergency Department
The Royal Children's Hospital Melbourne

Dear A/Prof Long,

Project Title: **Biomarkers in Sepsis (BASIS)**

HREC Reference Number: **HREC/101005/RCHM-2024**
RCH HREC Reference Number: **101005**

I am pleased to advise that the above project has received ethical approval from The Royal Children's Hospital Melbourne Human Research Ethics Committee (HREC).

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

HREC Approval Date: **21 May 2024**
Please note ongoing ethics approval is subject to the submission of a progress report on **21 May annually.*

Participating Sites:
Ethical approval for this project applies at the following sites:

Site Name
• Melbourne Children's Campus (incorporating The Royal Children's Hospital, Murdoch Children's Research Institute and the University of Melbourne Department of Paediatrics).
• Walter and Eliza Hall Institute

Approved Documents:
The following documents have been reviewed and approved:

Document	Version	Date
Protocol	1.1	13 May 2024
Parent Handout	1	22 February 2024

Request for a Waiver for the Requirement for Consent:
The Human Research Ethics Committee (HREC) reviewed the study in line with the NHMRC National Statement on Ethical Conduct in Human Research, including justification by the researchers to Section 2.3.10. It was deemed that the benefits of the research outweigh the risks posed by not obtaining consent, and it is impracticable to obtain express consent. As such a waiver of consent was granted to freeze and retain the discard blood samples taken during the routine blood sampling for longer than the normal archive period, in the RCH clinical pathology laboratory, until the time that consent is obtained and the samples are moved into the haematology research fridge.

Site Specific Assessment:
Site-specific governance authorisation must be obtained by each participating site before the study can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator at each site covered by this ethics approval to assist each site PI with obtaining governance approval to commence the project at that site.

Conditions of Ethics Approval:

- You are required to submit to the HREC:
    - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
    - A comprehensive Final Report upon completion of the project.
- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Safety monitoring and reporting in clinical trials involving therapeutic goods November 2016*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves exposure of persons to ionising radiation, you must ensure that your research is carried out in accordance with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for the 'Exposure of Humans to Ionizing Radiation for Research Purposes (2005)' (Radiation Protection series Publication No.8)
- The HREC, authorising institution and/or their delegate/s may conduct an audit of the project at any time.

Yours sincerely,

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