ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project Number: HREC/53920/Alfred-2019 (Local Reference: Project 271/19)

Project Title: RotEm-guided blood product in patients with Cirrhosis undergoing Invasive ProcEdures (RECIPE)

Coordinating Principal Investigators: Professor Stuart Roberts, Dr Ammar Majeed

*was considered under the National Mutual Acceptance (NMA) scheme by the Ethics Committee on **02-May-2019**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **19-June-2019**.*

It is the Coordinating Principal Investigator's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Coordinating Principal Investigator is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Coordinating Principal Investigator to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Coordinating Principal Investigator is required to submit

- A Progress Report on the anniversary of approval and on completion of the project.

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).

APPROVED DOCUMENTS

Documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Protocol: 271/19	2	04-Jun-2019
Werfen Instrumentation Laboratory ROTEM sigma Analyser Product Brochure	01	2017
Master Participant Information Sheet & Consent Form – Main	2	04-Jun-2019

APPROVED SITES

Approval is given for this research project to be conducted at the following sites and campuses:

- The Alfred hospital (Alfred Health) (Site PI: Prof Stuart Roberts)
- Austin Hospital (Austin Health) (Site PI: Prof Paul Gow)

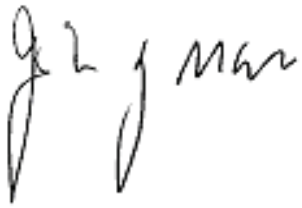
The Alfred Hospital Ethics Committee has approved the study but does not take responsibility for research governance processes at the participating sites. It is the responsibility of each participating site to create and implement research governance practices to adequately authorise, monitor and oversee the conduct of the study at their site.

Site-Specific Assessment (SSA)
SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site-Specific Assessment Form and a copy of this ethics approval letter must be submitted to the Research Governance Officer for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

The HREC wishes you and your colleagues every success in your research.

SIGNED:



Chair, Ethics Committee (or delegate)

Please quote project number and title in all correspondence