ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 312/22 (HREC/85433/Alfred-2022)

Project Title: Right Brachiocephalic Vein Origin Intravenous Access for Resuscitation of Adult Trauma Patients

Principal Researchers: Professor Mark Fitzgerald
Madeline Green

*was considered by the Ethics Committee on **23-Jun-2022**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **12-Aug-2022***

It is the Principal Researcher'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 Principal Researcher 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 Principal Researcher 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 Principal Researcher 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).

SPECIAL CONDITIONS

1. **All research projects approved by the Alfred Hospital Ethics Committee are subject to, and must be carried out in compliance with, the most recent applicable COVID-19 government and relevant institution's restrictions.**

CONSENT WAIVER

In accordance with the Office of the Health Services Commissioner's Statutory Guidelines on Research issued for the purposes of Health Privacy Principles 1.1(e)(iii) & 2.2(g)(iii), the Alfred Hospital Ethics Committee granted a consent waiver for the collection, use and disclosure of participants' health and personal information (as detailed in the Victorian Specific Module).

APPROVED DOCUMENTS

Document	*Version*	*Date*
Protocol:	2	18-Jul-2022
Opt-Out Brochure	2	18-Jul-2022
Data collection forms	1	28-May-2022
RBCV Access for Trauma (Participant)	-	-
RBCV Access for Trauma Data Collection Form for Controls	-	-

Documents Acknowledged	*Edition*	*Date*
Approval - ICU Committee	-	-
Approval - ED Committee	-	-
TGA ARTG Public Summary: Arrow Central Venous Catheter Sets, CS - CV Series - Catheter, central venous	-	25-Jul-2007
Product Information: Arrow Acute Haemodialysis Catheters	Rev 0	May-2020
Instructions for Use: Arrow Two-Lumen Hemodialysis Catheter Product	Rev 1	Apr-2021
RSO Report Alfred Health		10-Jun-2022

APPROVED SITES

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

1. The Alfred (Alfred Health) Site PI: Professor Mark Fitzgerald

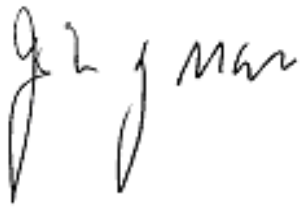
The Alfred Hospital Ethics Committee has approved the study but does not take responsibility for research governance processes at the participating sites. It is the responsibility of each participating site to create and implement research governance practices to adequately authorise, monitor and oversee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



Professor John J. McNeil
Chair, Ethics Committee

Please quote project number and title in all correspondence