ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: HREC/17/Alfred/180 (Local Reference: Project 552/17)

Project Title: Doxycycline aS A cardioprotective agent in ST-eLeVAtion myocardial infarction: a pilot study addressinG pre- rEperfusion administration.

Principal Researcher: Dr William Chan

*was considered under National Mutual Acceptance (NMA) by the Ethics Committee on **23-Nov-2017**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **09-May-2018***

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 *(forms to be provided)*;

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

Alfred Health: Only researchers who have current, acceptable GCP training and provided evidence of the training to the Alfred Health Ethics & Research Governance Office can be involved in this trial.

Approved documents

Documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Protocol: SALVAGE MI	5.0	29 March 2018
Product Information: Doxycyclin -ratiopharm® SF		April 2014
Master Participant Information and Consent Form – Brief: Alfred and Sunshine Hospitals	2	14 April 2018
Master Participant Information and Consent Form – Detailed: Alfred and Sunshine Hospitals	3	07 May 2018
RSO Report: Alfred Health		03 November 2017
RSO Report: Western Health – Sunshine Hospital		15 February 2018

Approved Sites:
Approval is given for this research project to be conducted at the following sites and campuses:
Alfred Health – The Alfred
Western Health – Sunshine Hospital

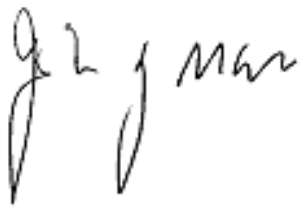
The HREC notes that it is the responsibility of the researchers to ensure that they and any other people or entities involved in the conduct of the study comply with all applicable laws regarding the conduct of the study, including laws regarding the recruitment of participants who lack the capacity to provide informed consent, of the jurisdiction in which the study will be conducted.

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