ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project Number: HREC/58991/Alfred-2019 (Local Reference: Project 662/19)

Project Title: Lignocaine in gastroscopy - LIG Trial

Principal Investigator: Professor Paul Myles

*was considered by the Ethics Committee on **21-November-2019**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **13-January-2020**.*

It is the 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 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 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 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).

SPECIAL CONDITION

1. **Clinical trial registration ID to be provided, prior to the recruitment of the first participant, when the trial is registered on a Primary Registry in the World Health Organization Registry Network.**

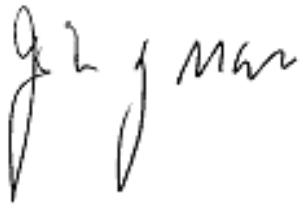
APPROVED DOCUMENTS

Documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Protocol	1	07-Jan-2020
Participant Information and Consent Form	1	07-Jan-2020
Letter to potential participants – patients scheduled to undergo a gastroscopy at The Alfred	1	07-Jan-2020

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