



## ETHICS COMMITTEE CERTIFICATE OF APPROVAL

*This is to certify that*

**Project No:** 328/16

**Project Title:** Propofol for Migraine Treatment in Emergency Department (ProMTED study)

**Principal Researcher:** A/Professor Biswadev Mitra

**Protocol:** ProMTED study    **Version:**1.0    **dated:** 25-Jul-2016

**Participant Information and Consent Form dated:** 25-Jul-2016

*was considered by the Ethics Committee on **28-Jul-2016**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **19-Aug-2016***

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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

None

SIGNED:

**Professor John J. McNeil  
Chair, Ethics Committee**

***Please quote project number and title in all correspondence***