MELBOURNE HEALTH

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MELBOURNE HEALTH HUMAN RESEARCH ETHICS COMMITTEE

ETHICAL APPROVAL

Dr Irene Ng
Department of Anaesthesia and Pain Management
Royal Melbourne Hospital
300 Grattan Street
Parkville VIC 3050

14 February 2017

Dear Dr Ng,

HREC Reference Number: HREC/16/MH/341
Melbourne Health Site Reference Number: 2016.247
Project Title: The use of Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE) for pre-oxygenation in neurosurgical patients: a randomised controlled trial

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I am pleased to advise that the above project has **received ethical approval** from the Melbourne Health Human Research Ethics Committee (HREC). The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

HREC Approval Date: 12 February 2017

Ethical approval for this project applies at the following sites:

Site
Royal Melbourne Hospital, Parkville, VIC.

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Protocol	2	10 January 2017
Master Patient Information Sheet and Consent Form	2	10 January 2017
Case Report Form	-	16 August 2016.

Governance Authorisation:

Governance Authorisation is required at each site participating in the study before the research project can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator for each site covered by this ethics approval for inclusion in the site specific assessment application.

Conditions of Ethics Approval:

- You are required to submit to the HREC:
    - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
    - A comprehensive Final Report upon completion of the project.
- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.

If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).

Please note: Template forms for reporting Amendments, Adverse events, Annual/Final reports, etc. can be accessed from: https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials.

Waiver of consent wording, if applicable:
[Request for a Waiver of the Requirement for Consent- The request for a waiver of the requirement of consent is approved.]

If applicable, for sites in NSW only-NCAT approval wording:
[NSW sites]-As your trial anticipates recruiting participants in NSW who may be incapable of providing valid consent to participate for themselves, [we / the HREC] suggest that you make yourself aware of the provisions of the *Guardianship Act* 1987 (NSW). Prior to commencing your trial in NSW, you may need to make an application to the NSW Civil and Administrative Tribunal (NCAT) for approval for your trial to proceed as well as to provide direction on the appropriate consent mechanism. Please note that the Act contains serious penalties for conducting clinical trial research on non-competent participants without proper authorisation.

The HREC may conduct an audit of the project at any time.

Yours sincerely,

Prof Peter Colman
Chair – Melbourne Health Human Research Ethics Committee (HREC)