Albury Wodonga Health Human Research Ethics Committee

ETHICS APPROVAL

Mr Dhruv Kapoor
485 McDonald Road
Lavington NSW 2641
Australia

5 November 2020

Dear Mr Dhruv Kapoor,

Project Title	Deep versus awake removal of the laryngeal mask airway after tonsillectomy in children and its effect on emergence delirium in the PACU: a randomised controlled trial
Project ID	66918
Review Reference	HREC/66918/AWHEC-2020-233510(v2)
Local Reference Number	458/20/8

I am pleased to advise that the above project has received ethical approval from Albury Wodonga 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 (NHMRC) *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).

Participating Sites

Ethical approval for this project applies at the following site(s): Albury Wodonga Health, Victoria/New South Wales.

Approved Documents

The following documents have been reviewed and approved:

Document Type	File Name	Date	Version
Victorian specific module (VSM)	VSM Form Completed	14/09/2020	Latest
PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	Tracked and edited consent form	14/09/2020	Latest
Protocol	Project Outline/Protocol	14/09/2020	Latest

Research Governance Authorisation

Research governance/site specific assessment (SSA) authorisation must be obtained by each participating site 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 of each site covered by this ethics approval. A copy must be included in each site's research governance/SSA application.

Conditions of Ethics Approval

1. 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 scheduled date. 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.
2. 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.
3. Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016).
4. Notify the reviewing HREC of your inability to continue as Principal Investigator.
5. Notify the reviewing HREC of the failure to commence the research project within 12 months of the HREC approval date or if a decision is taken to end the research project at any of the sites prior to the expected date of completion.
6. Notify the reviewing HREC of any matters which may impact the conduct of the research project.
7. 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).
8. The HREC, authorising institution and/or their delegate(s) may conduct an audit of the research project at any time.

Research Project Including NSW Site(s)

As the research project anticipates recruiting participants in NSW who may be incapable of providing valid consent to participate for themselves, you should make yourself aware of

the provisions of the *Guardianship Act 1987* (NSW). Prior to commencing the research project in NSW, you may need to make an application to the NSW Civil and Administrative Tribunal (NCAT) for approval for the research project 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 AWHHREC wishes you the best with your research project. If you have any queries please don't hesitate to contact Jessica Borgh, AWHHREC Administration Officer at jessica.borgh@awh.org.au.

Yours sincerely,

Dr Glenn Davies
Chair, Albury Wodonga Health Human Research Ethics Committee