Office of Research and Ethics
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31 July 2024

A/Prof Paul Buntine
Department of Emergency
8 Arnold St, Box Hill, Vic 3128

Dear A/Prof Buntine,

Study Title: A randomised controlled trial comparing Penthrox (methoxyflurane) with nitrous oxide for painful emergency medicine procedures

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Principal Investigator: Paul Buntine
Associate Investigator/s: Patrick Owen, Peter Stone, Gael Sommerville, Jeremy Szmerling, Joseph Miller, Liam Hackett, Emogene Aldridge & Courtney Cini
Other Personnel: Emily Schembri (Biostatistician)
Eastern Health Reference Number: E24-007-106072

Thank you for your correspondence on 29th July 2024 addressing the matters raised in the HREC's letter dated 16th May 2024 following the ethical review of the above project at its meeting held on 16th May 2024. Final correspondence was received on 31 July 2024 including series of amendments and clarifications.

I am pleased to advise that the above study has received full ethical approval from the Eastern Health Human Research Ethics Committee (HREC). The study has received full governance authorisation also from the Office of the Chief Executive Officer or delegate at Eastern Health and may commence at the nominated site.

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2023) (**National Statement**). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (**NHRMC**) National Statement and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles (HPP's) described in the Health Records Act 2001 (Vic).

HREC Final Approval Date: 30 July 2024
Research Governance Authorisation: 31 July 2024
Ethical approval for this project applies at the following site/s: Box Hill Hospital

Approved Documents:

The following documents have been reviewed and **approved** by the HREC:

Document	Version	Dated
Human Research Ethics Application (HREA) - Review Reference: HREC/106072/EH-2024-440722(v3)	3	29Jul2024
Protocol	3	26Jul2024
Participant Information Sheet and Consent Form (PICF) - Adult	3	26Jul2024
Participant Information Sheet and Consent Form (PICF) - Child	3	26Jul2024
Case Report Form (CRF)	2	26Jun2024
Victorian Specific Module (VSM) - Review Reference: VSM/106072/EH-2024-440608(v1)	1	26Jul2024

The following documents have been reviewed and authorised / noted by the Office of Research and Ethics (Research Governance):

Document	Version	Dated
Site Specific Assessment (SSA) – Review Reference: SSA/106072/EH-2024-440723(v1)	1	29Jul2024

Approval is subject to:

1. The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement.
2. (If applicable) For clinical trials where Eastern Health is the Sponsor, you are required to contact the Office of Research and Ethics to organise submission of the electronic Clinical Trial Notification (e-CTN) to the TGA. This must be completed before commencement of your project. It is the Principal Investigator's responsibility to ensure that copies of the complete submitted e-CTN and TGA issued acknowledgement are included in the Site Study File for the project.
3. (If applicable) Submit a copy of this letter to the person responsible for radiation safety at Eastern Health. This condition only applies if the project involves **exposure to ionising radiation that exceeds dose constraints, and the Medical Physicist's report has advised that the project needs to be added to the site's Licence** for Research Involving Human Volunteers issued by the Department of Health Radiation Safety Section (for more information, visit http://www.health.vic.gov.au/radiation/). **Note**: If the Medical Physicist's report has advised that the project needs to be added to the site's licence, the project cannot commence at site until you have confirmed that the project has been added to the site's licence.
4. Immediate notification to the Office of Research & Ethics of any serious adverse events on participants.
5. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project.
6. Immediate notification to the Office of Research and Ethics of any breach of data, breach of participant's rights and participant complaints.
7. Notification of any changes to personnel on the study.

8. Notification and reasons for ceasing the project prior to its expected date of completion.
9. Submission to the HREC of any proposed modifications to the project or documents as approved by the HREC and noted above.
10. Submission of an **annual report due in February each year** for the preceding calendar year, for the duration of the study. Further guidance can be found https://www.easternhealth.org.au/research-ethics/guidance
11. Submission of a **final report** and papers published on completion of the project.
12. Projects may be subject to an audit or any other form of monitoring by the Eastern Health Office of Research & Ethics at any time.

Confidentiality, Privacy & Research:
Research data stored on personal computers, USBs and other portable electronic devices must not be identifiable. No patients' names or UR numbers must be stored on these devices. Electronic storage devices must be password protected or encrypted. The conduct of research must be compliant with the conditions of ethics approval and Eastern Health policies.

Publications:
Publications are very important for disseminating research and demonstrating the research activity of investigators and their institutions. Publications provide evidence of the contribution that participants, researchers and funding sources make. It is therefore important that the role of Eastern Health including the investigator's Eastern Health affiliation (if appropriate) is provided in publications.

Composition of the HREC
We confirm at the meetings at which the above project was considered, the Committee fulfilled the requirements of the NHMRC National Statement in that it contained men and women encompassing different age groups and included people in the following categories:

HREC Members
Chairperson
Person/s bringing a broader community or consumer perspective
Lawyer
Person/s fulfilling a Pastoral Care Role
Person/s with knowledge of and current experience in the professional care or treatment of people
Person/s with Current Research Experience

Please always quote the Eastern Health Reference Number **E24-007-106072** in all future correspondence.

Yours sincerely

Amy Tang
Digitally signed by Amy Tang
Date: 2024.07.31 16:13:46 +10'00'

Research Ethics and Governance Officer, Eastern Health Office of Research and Ethics
On behalf of
1. Eastern Health Human Research Ethics Committee (Ethics Approval)
2. Executive Director of Eastern Health Institute (Site Research Governance Authorisation)