



**ST VINCENT'S  
HOSPITAL**  
MELBOURNE

A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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13 January 2023

Doctor Harsh Dubey  
Department of Anaesthesia and Acute Pain Medicine  
St Vincent's Hospital Melbourne

Dear Dr Dubey,

**ERM ID Number: 87104**  
**SAGE ID Number: 2022/PID06427**  
**St Vincent's HREC Reference: 181/22**

***Title: 'Effect of ERAS-instigated preoperative carbohydrate drinks on gastric state and cardiac output'***

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I am pleased to advise that the above project has received **ethical approval** from the St Vincent's Hospital Melbourne Human Research Ethics Committee (HREC)

**HREC Approval Date: 13 January 2023**

St Vincent's Hospital Melbourne HREC is accredited by the National Health and Medical Research Council (NHMRC) under the single ethical review system. The 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, updated 2018) 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).

Approval is given in accordance with the research conforming to the National Health and Medical Research Council Act 1992 and the National Statement on Ethical Conduct in Human Research (2007, updated 2018)

**Ethical approval for this research project has been given at the following sites:**

- St Vincent's Hospital Melbourne, VIC

**Please note that each participating site will require governance approval (SSA approval) prior to commencement of this research project.**

**Site-Specific Assessment - Governance**

SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

You are now required to forward this HREC approval letter with an electronic copy of the approved documents named above to the Principal Investigator(s) and the Research Governance Officer (s) at each participating site covered by this HREC approval. Each participating site must issue governance approval of the project before the study can commence at individual sites.

*Approval is subject to:*

- **An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the 01 May each year for the duration of the project. Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of the project by the HREC.**
  - 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 on Ethical Conduct in Human Research 2007 (including all updates)
  - The Principal Researcher is to notify the Research Governance Unit of all significant safety issues in accordance with the *NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods (including all updates)*.
  - Submit an Annual Safety Report for the duration of the project.
  - Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
  - Notification and reasons for ceasing the project prior to its expected date of completion;
  - Submit to the reviewing HREC for approval of any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s, Investigator Brochure and other study materials.
  - Submission of reviewing HREC approval for any proposed modifications to the project.
  - Submission of a final report and papers published on completion of project.
  - Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

The following documents have been reviewed and approved:

**Approved documents:**

Document	Version	Date
VSM	-	-
Study Protocol	-	-
Master PICF – Main	1.4	01 Dec 2022

**Acknowledged Documents:**

Document	Version	Date
HREA	-	-
Academic Review Process	-	-
CV – Harsh Dubey	-	-

CV – Adam Lipszyc	-	-
CV – Brian Cowie	-	-
CV – Tuong Phan	-	-
GCP – Harsh Dubey	-	07 Jan 2022
GCP – Adam Lipszyc	-	15 Sep 2021
GCP – Brian Cowie	-	21 May 2021
GCP – Tuong Phan	-	28 Oct 2022

**ERM ID Number: 87104**  
**SAGE ID Number: 2022/PID06427**  
**St Vincent’s HREC Reference: 181/22**  
**Please use the above numbers in all correspondence.**

The HREC wishes you and your colleagues every success in your research.

Yours sincerely,

**Alexander Devlin**  
Administrative Assistant  
Research Governance Unit  
St Vincent’s Hospital (Melbourne)