



14 May 2019

Dr Ana Licina
Department of Anaesthesia
St Vincent's Private Hospital Melbourne

Dear Dr Licina

Project ID: 49096

St Vincent's local reference number: LRR 003/19

Study Title: Early Nutrition Support in Neurosurgical Patients - Prospective Cohort Study Based on Post-Operative Gastrointestinal Recovery Scores.

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 July 2018)*

This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Research Involving Humans 2007 (updated July 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 Date: 14 May 2019

Ethical approval is given for this research project to be conducted at the following sites:

- St Vincent's Private Hospital, Melbourne

This approval will be ratified by St Vincent's Hospital (Melbourne) HREC at the next meeting.

Approved documents

The following documents have been reviewed and approved:

Document	Version	Date
Human Research Ethics Application (Project ID: 49096)	1	16 December 2018
Victorian Specific Module	-	16 December 2018
Prospective Cohort Study- Protocol	1.7	19 March 2019
Master Participant Information Sheet/Consent Form	1.3	19 March 2019
I-FEED Scoring System	1.2	19 March 2019

Survey of Medical Attitudes to Post-op Fasting	1.1	19 March 2019
Survey of Nursing Attitudes to post-operative fasting	1.3	19 March 2019
Data Collection Form	-	-
Letter of Acknowledgement from SVPHM	-	27 March 2019

Noted Documents

Document	Version	Date
Curriculum Vitae – Dr Ana Licina	-	-

Terms of approval:

1. It is the responsibility of the Principal Researcher to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as specified in the application.
2. 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).
3. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
4. Amendments to the approved project: Changes to any aspect of the project require the submission of a Request for Amendment to the Low Risk Research Sub-committee and must not begin without written approval. Substantial variations may require a new application.
5. Future correspondence: Please quote the reference number and project title above in any further correspondence.
6. **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.**
7. Final report: A Final Report must be provided at the conclusion of the project.
8. Monitoring: Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

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.

We wish you well with your project.

Yours sincerely,

R. Akshaya

Ms Akshaya Ravi
Administrative Assistant
Research Governance Unit
St Vincent's Hospital (Melbourne)