ST VINCENT'S HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

St Vincent's Hospital (Melbourne) Limited
ABN 22 052 110 755

41 Victoria Parade Fitzroy VIC 3065
PO Box 2900 Fitzroy VIC 3065

Telephone 03 9288 2211
Facsimile 03 9288 3399
www.svhm.org.au

13 May 2021

Dr Tuong Phan
Department of Anaesthesia and Acute Pain Medicine
St Vincent's Hospital Melbourne

Dear Dr Phan,

Project ID: 69987
St Vincent's local reference number: LRR 286/20
Short title: *'(GUILE STUDY) - Gastrointestinal Ultrasound Ileus Study'*

'The use of point of care ultrasound (POCUS) in detecting post-operative ileus'

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: 13 May 2021

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

- St Vincent's Hospital Melbourne, VIC
- Peter MacCallum Cancer Centre, VIC
- Austin Hospital, VIC

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
Victorian Specific Module	-	-

GUILE Protocol	1.2	16 Mar 2021
Master Participant Information Sheet/Consent Form	1.2	16 Mar 2021
Research Collaboration Agreement – PMCC	-	13 May 2021
Research Collaboration Agreement – Austin Health	-	13 May 2021

Acknowledged Documents

Document	Version	Date
Human Research Ethics Application – HREC/69987/SVHM-2021-254168(v4)	-	-
Budget	1.0	05 Jan 2017
Curriculum Vitae – Tuong Phan	-	-
Curriculum Vitae – Craig Delavari	-	-
Curriculum Vitae – Ankur Sidhu	-	-
Curriculum Vitae – Basil D'Souza	-	-
Curriculum Vitae – Katrina Hall	-	-
Curriculum Vitae – Tom Tiang	-	-
Curriculum Vitae – Louisa-Rose Bhanabhai	-	-
Curriculum Vitae – Ian Richardson	-	-
Good Clinical Practice – Tuong Phan	-	20 Oct 2019
Good Clinical Practice – Craig Delavari	-	07 Oct 2020
Good Clinical Practice – Ankur Sidhu	-	22 May 2018
Good Clinical Practice – Basil D'Souza	-	07 Aug 2018
Good Clinical Practice – Katrina Hall	-	22 Oct 2020
Good Clinical Practice – Tom Tiang	-	21 Dec 2020
Good Clinical Practice – Louisa-Rose Bhanabhai	-	13 Mar 2021
Good Clinical Practice – Ian Richardson	-	25 May 2018

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.

If 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.

We wish you well with your project.

Yours sincerely,

Alexandra Braun
Low Risk & QA Officer
Research Governance Unit
St Vincent's Hospital (Melbourne)