



**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 9231 2211
Facsimile 03 9231 3399
www.svhm.org.au

31 March 2017

Mr Michael Hii
Department of General Surgery, Hepatobiliary and Upper Gastrointestinal
St Vincent's Hospital (Melbourne)

Dear Mr Hii,

SERP HREC Reference Number: HREC/16/SVHM/153
St Vincent's HREC Ref: HREC 122/16

'A randomised controlled trial investigating the effect of humidified warm CO2 insufflation during laparoscopic and open abdominal surgeries'

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)

Approval Status: FINAL

Period of Approval: 31 March 2017 – 31 March 2021

This HREC is accredited by the Consultative Council for Human Research Ethics under the single ethical review system. The HREC has ethically approved this research according to the Memorandum of Understanding between the Consultative Council and the participating organisations conducting the research.

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 May 2015*)

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

- **St Vincent's Hospital Melbourne**

Approval is subject to:

- 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 (*updated May 2015*)
- Immediate notification to the Research Governance Unit of any serious adverse events on participants.

- 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 an annual report, due on the anniversary date of approval, for the duration of the study. Failure to comply with this requirement may result in suspension of the project by the HREC.
- 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
National Ethics Application Form (AU/1/986C210)	2.2 (2014)	09 Mar 2017
Victorian Specific Module	Jan 2015	15 Mar 2017
Letter of Support signed by Mr Simon Banting	N/A	14 Mar 2017
Research Plan	1	07 Mar 2017
Humigard Brochure – Fisher & Paykel Laparoscopic Humidification System	Rev C	© 2011
SVHM Participant Information and Consent Form for Self - Open Arm	1	23 Mar 2017
SVHM Participant Information and Consent Form for Person Responsible – Open Arm	1	23 Mar 2017
SVHM Participant Information and Consent Form for Self - Laparoscopic Arm	1	23 Mar 2017
SVHM Participant Information and Consent Form for Person Responsible - Laparoscopic Arm	1	23 Mar 2017
Post-Operative Pain Questionnaire – Open Arm	1	07 Mar 2017
Post-Operative Pain Questionnaire - Laparoscopic Arm	1	07 Mar 2017

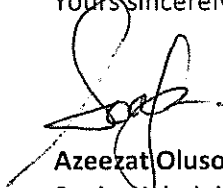
Noted documents:

Document	Version	Date
CV – Mr Michael Hii	N/A	N/A
CV – Dr Alexander Brown	N/A	N/A
CV – Mr Adrian Fox	N/A	16 Feb 2016

<p>HREC Reference Number: HREC/16/SVHM/153 St Vincent's HREC Ref: HREC 122/16</p>
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The HREC wishes you and your colleagues every success in your research.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'A. Onipe', with a large loop at the top and a horizontal stroke across the middle.

Azezat Olusola Onipe
Senior Administrative Officer and HREC Secretary
Research Governance Unit
St Vincent's Hospital (Melbourne)

