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

St Vincent's Hospital Sydney Limited
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Darlinghurst NSW 2010

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INSTITUTIONAL REVIEW BOARD STATEMENT

Gastroenterologist Perceptions of Faecal Microbiota Transplantation

(Manuscript No 17929)

The clinical trial (ClinicalTrials.gov Identifier: NCT01896635) this study (involving a voluntary anonymous survey of gastroenterology colleagues) was performed in conjunction with was reviewed and approved by the St Vincent's Hospital Human Research Ethical Committee.

Regards

Michael Kamm.

Professor of Gastroenterology

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09 April 2013

Dr Alissa Walsh
Gastroenterology Department
Xavier, Level 4
St Vincent's Hospital
Darlinghurst NSW 2010

SVH File Number: 13/047
Project Title: Faecal Microbiota Transplantation (FMT) for Chronic Active Ulcerative Colitis (FOCUS Study) – A Randomised Double Blind Controlled Study of Efficacy & Safety
(HREC Reference Number: *HREC/13/SVH/69)*

Thank you for submitting the above project for ethical and scientific review. The project was first considered by the St Vincent's Hospital HREC at its meeting held on **14 March 2013.** This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the Committee at an Executive meeting on **09 April 2013** has granted ethical and scientific approval of the above **multi centre** project.

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The project is approved to be conducted at:

- St Vincent's Hospital Sydney
- Nambour Hospital
- Bankstown-Lidcombe Hospital

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documentation has been reviewed and approved by the HREC:

- Protocol, Version 1dated 22 February 2013
- Letter of Invitation, Version 1 dated 22 February 2013
- Study Participant Instruction Sheet on Enema Storage & Administration and Faecal Sample of Efficacy & Safety, Version 1 dated 22 February 2013
- Study Participant Information Sheet and Consent Form, Version 2 dated 27 March 2013
- "Healthy Faecal Donor" Information Sheet and Consent Form, Version 2 dated 27 March 2013
- Case Report Form for Study Participants, Version 1 dated 22 February 2013
- Patient Diary for Study Participants, Version 1 dated 22 February 2013
- Mayo Scoring System
- IBDQ
- Ulcerative Colitis Endoscopic Index of Severity (UCEIS©)

Please forward the CTN to the Research Office for signature.

The St Vincent's Hospital signed CTN form has been forwarded to the Research Governance Officer for Site Specific Authorisation.

The National Ethics Application Form (NEAF) document reviewed by the HREC was NEAF **AU/1/8871113.**

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of the HREC Executive Committee meeting and expires on **09 April 2018.** The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.

- The Co-ordinating Investigator will provide an annual progress report beginning in **April 2014**, to the HREC as well as a final study report at the completion of the project in the specified format.

- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by study participants regarding the conduct of the study.

- Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review, in the specified format.

- The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.

- Projects that are undertaken by Investigators holding an academic appointment (including conjoint appointments) or by students as part of a University course are also required to contact the relevant University HREC to seek advice from the University regarding their requirements.

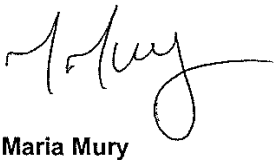
Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg Australian Clinical Trial Registry www.actr.org.au).

Should you have any queries about your project please contact the Research Office, Tel: 8382-2075, email research@stvincents.com.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website: www.stvincents.com.au/researchoffice or internal at http://exwwwsvh.stvincents.com.au/researchoffice

Please quote **SVH File Number: 13/047** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely



Maria Mury
Acting HREC Executive Officer
Research Office
L6 de Lacy Building

CC: Sudarshan Paramsothy
Filename: D/2013/19855