



South Western Sydney Local Health District acknowledges the traditional owners of this land.

**\*\*AMENDMENT TO LETTER DATED 7 NOVEMBER 2018\*\***

17 January 2019

A/Professor Susan Connor  
Gastroenterology and Hepatology  
Liverpool Hospital  
Locked Bag 7103  
LIVERPOOL BC NSW 1871

**\*\*\*THIS LETTER CONSTITUTES ETHICAL APPROVAL ONLY. THIS RESEARCH PROJECT MUST NOT COMMENCE AT A SITE UNTIL SEPARATE AUTHORISATION FROM THE CHIEF EXECUTIVE OR DELEGATE OF THAT SITE HAS BEEN OBTAINED. \*\*\*\***

Dear A/Professor Connor,

**Project Title:** Therapeutic drug monitoring – Correlation between biologic trough levels and fistula healing in patients with Crohn’s disease  
**HREC Reference:** LNR/18/LPOOL/404  
**SSA reference Number:** LNRSSA/18/LPOOL/437  
**Local Project Number:** HE18/261

Thank you for your Summary Sheet for an Amendment to an Approved Protocol dated 6 November 2018, requesting approval from the *South Western Sydney Local Health District Human Research Ethics Committee*. I am pleased to inform you that the following documents are approved for the above-mentioned study:

Document	Date
Summary Sheet for an Amendment to an Approved Protocol	06.11.2018
Protocol Version 4	02.11.2018

Approval has been granted for the following site(s):

- Royal Prince Alfred Hospital
- Liverpool Hospital
- St Vincent’s Hospital

Conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
  - any serious or unexpected adverse events; and
  - unforeseen events that might affect continued ethical acceptability of the project.
2. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each sites so that they can notify their Research Governance Officer.
3. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.

4. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
5. The Principal Investigator must reassure participants about confidentiality of the data.
6. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Jessica Grundy', with a horizontal line underneath.

**Jessica Grundy**  
Research Ethics and Governance Manager  
Research and Ethics Office  
South Western Sydney Local Health District

**From:** Susan Connor (South Western Sydney LHD)  
**Sent:** Friday, 13 September 2019 7:21 AM  
**To:** Aimee Lee (South Western Sydney LHD)  
**Subject:** Fwd: 2019/ETH09899: Amendment - Addition of Site - Approved

Susie Connor  
Head IBD Service, Dept of Gastroenterology  
Liverpool Hospital  
Working together to provide expert individualised care for Crohn's and Colitis

Begin forwarded message:

**From:** [no\\_reply@regis.health.nsw.gov.au](mailto:no_reply@regis.health.nsw.gov.au)  
**Date:** 12 September 2019 at 6:16:11 pm AEST  
**To:** [susan.connor1@health.nsw.gov.au](mailto:susan.connor1@health.nsw.gov.au)  
**Cc:** [bonita.gu@unsw.edu.au](mailto:bonita.gu@unsw.edu.au), [Sudarshan.Paramsothy@health.nsw.gov.au](mailto:Sudarshan.Paramsothy@health.nsw.gov.au)  
**Subject:** 2019/ETH09899: Amendment - Addition of Site - Approved  
**Reply-To:** [SWSLHD-Ethics@health.nsw.gov.au](mailto:SWSLHD-Ethics@health.nsw.gov.au)

Date of Decision Notification: 12 Sep 2019

Dear Associate Professor Susan Connor,

**2019/ETH09899: Therapeutic drug monitoring – Correlation between biologic trough levels and fistula healing in patients with Crohn’s disease**

The Amendment has been reviewed on 12 Sep 2019, by the Administration Officer as delegated by the Executive Officer and has been **approved**.

Amendment type: **Addition of a New Site**

- Concord Repatriation General Hospital

PI name:

- Dr Sudarshan Paramsothy

PI email:

- [Sudarshan.Paramsothy@health.nsw.gov.au](mailto:Sudarshan.Paramsothy@health.nsw.gov.au)

The following documentation is included in this approval:

- Notification of an amendment to a research study - Addition of a New Site

It is noted that the South Western Sydney Local Health District Human Research Ethics Committee is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC).

**This email constitutes ethical and scientific approval only.**

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below.

Kindest regards,

**Malina Peng**

Administrative Officer | **Research Directorate**

South Western Sydney Local Health District (SWSLHD)

Locked Bag 7103 Liverpool BC NSW 1871

Tel 02 8738 8304 | Fax 02 8738 8310 |

E-mail: [SWSLHD-Ethics@health.nsw.gov.au](mailto:SWSLHD-Ethics@health.nsw.gov.au)

<https://www.swslhd.health.nsw.gov.au/ethics/>

**Research Webinars!**

The Research Directorate is holding weekly webinars each Wednesday at 2pm via Pexip. The webinars cover REGIS and research application information for SWSLHD. For more information on how to attend the webinars and view material for previous webinars, please click <https://www.swslhd.health.nsw.gov.au/ethics/training.html>