Health
South Western Sydney
Local Health District

Research and Ethics Office
Leadership · Quality · Governance
Locked Bag 7103, LIVERPOOL BC, NSW, 1871
Phone: 02 8738 8304
Facsimile: 02 8738 8310
http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html

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

5 October 2017

Dr Susan Connor
Department of Gastroenterology
Liverpool Hospital
CC: Sasha Ruban

*****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 Dr Connor,

Project Title:	**Controlled trial of a decision aid for ulcerative colitis patients: Enhancing patients' quality of life, empowerment, quality of decision making and disease control**
HREC Reference:	**HREC/15/LPOOL/358**
SSA Reference:	**SSA/15/LPOOL/434**
Local Project Number:	**HE15/199**

Thank you for your Summary Sheet for an Amendment to an Approved Protocol dated 30 August 2017, 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	30.08.2017

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

- Liverpool Hospital
- Concord Hospital
- St Vincent's Hospital (Sydney)
- St George Hospital
- Wollongong Hospital
- Royal Adelaide Hospital
- Flinders Medical Centre
- St Vincent's Hospital (Victoria)
- Box Hill Hospital (Eastern Health - Victoria)
- Alfred Hospital (Victoria)
- Monash Hospital (Victoria)
- Royal Brisbane Hospital (QLD)
- Mater Hospital (QLD)
- Royal Prince Alfred Hospital (NSW)
- The Queen Elizabeth Hospital (SA)
- Blacktown Hospital (NSW)
- Royal North Shore Hospital (NSW)
- Wagga Wagga Private Clinic

Please find enclosed the following documents:

2 x External Entity Agreements for Wagga Endoscopy Centre

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.

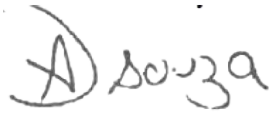
3. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.

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,



Annamarie D'Souza
Manager, Research and Ethics Office
South Western Sydney Local Health District