NSW GOVERNMENT Health
South Western Sydney Local Health District
Research and Ethics Office
Leadership · Quality · Governance
Locked Bag 7103, LIVERPOOL BC, NSW, 1871
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http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html

18 October 2015

Dr Susan Connor
Department of Gastroenterology
Liverpool Hospital

*****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:	**15/199**

Thank you for your response dated 24 August 2015 to our request for further information dated 17 August 2015. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the Committee has granted ethical approval of the above project.

The following documentation has been reviewed and approved:

Please ensure for all future documents submitted for review include a document version number, document date and page numbering.

Monitoring Requirements:
(National Statement Chapters 2.1 and 5.5)

- The Committee has classified this project as:

  Low Risk

- Monitoring required for this study will be:
  - Submission of Annual Progress Reports with the first report due **18 October 2016 and annually thereafter for the duration of the approval period**

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

Please note the following 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.

7. The Principal Investigator is responsible for ensuring the research project is conducted in line with relevant NSW Health, South Western Sydney Local Health District and Hospital policies available from: http://www.sswahs.nsw.gov.au/swslhd/ethics/policies.html

HREC approval is valid for (5) years. If the study is ongoing at the conclusion of the five year approval period, a full resubmission may be required. Ethics approval will continue during the re-approval process.

The South Western Sydney Local Health District Human Research Ethics Committee has been accredited by the NSW Ministry of Health to provide single ethical and scientific review of research proposals conducted within the NSW public health system and Victorian and Queensland Public Health Organisations participating in the Mutual Acceptance Scheme.

You are reminded that 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. It is your responsibility to forward a copy of this letter together with any approved documents as enumerated above, to all site investigators for submission to the site's Research Governance Officer.

Should you have any queries about your project please contact **Annamarie D'Souza** on the telephone number listed above. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SWSLHD website: *http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html*

Please quote the Local HREC reference **15/199** in all correspondence. The HREC wishes you every success in your research

Yours faithfully

AD 20039

for **Professor Jeremy Wilson**
Chairperson, SWSLHD Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.