Health
South Western Sydney
Local Health District
Ethics and Research Governance Office
Locked Bag 7017, LIVERPOOL BC, NSW, 1871
Phone: 02 8738 8304
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http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html

24th May 2012

Dr Susan Connor
Department of Gastroenterology
Liverpool Hospital
Locked bag 7130
Liverpool BC NSW 1871

Dear Dr Connor,

*******THIS LETTER CONSTITUTES ETHICAL APPROVAL ONLY. YOU MUST NOT COMMENCE THIS RESEARCH PROJECT UNTIL SEPARATE SITE SPECIFIC AUTHORISATION HAS BEEN GRANTED*******

Project title:	**Prospective single-blinded single-centre randomized controlled trial in comparing Moviprep, a polyethylene glycol-based solution with PrepKit C, a combined polyethylene glycol and sodium picosulfate-based solution in the preparation of patients for colonoscopy.**
HREC Reference:	**HREC/12/LPOOL/108**
Project number:	**12/068**

Thank you for correspondence dated 26th April 2012 to our conditional approval letter dated 18th April 2012. This HREC 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:

- NEAF Application Form, submission code AU/1/FD9C012
- Study Protocol, Version 1.0, dated 14th March 2012
- Participant Information Sheet and Consent Form (For Collection of Human Tissue), Version 2.0, dated 26.4.2012
- Colonoscopist – Bowel Cleansing Assessment Form, Version 2.0, dated 26.4.2012
- Participant Questionnaire, Version 2.0, dated 26.4.2012
- Split Bowel Preparation for Colonoscopy using MOVIPREP, Version 1.0, dated 14th March 2012
- Split Bowel Preparation for Colonoscopy using PREP KIT C, Version 1.0, dated 14th March 2012

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

Approval is valid for the following Site only:

- Liverpool Hospital

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.

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.

HREC approval is valid for (5) years subject to the supply of an annual progress report which will be required by 24th May, 2013.

Should you have any queries about your project please contact **Merela Ghazal** 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.swsahs.nsw.gov.au/areaser/ethics/default.asp

You are reminded that this letter constitutes ethical approval only. You must not commence this research project until separate site specific authorisation has been granted.

Please quote the Local HREC reference **12/0068** in all correspondence.

The HREC wishes you every success in your research

Yours faithfully

Professor Jeremy Wilson
Chairperson
SWSLHD Human Research Ethics Committee