Government of South Australia
SA Health

Central Adelaide Local Health Network
Human Research Ethics Committee (TQEH/LMH/MH)
The Queen Elizabeth Hospital
Basil Hetzel Institute DX465101
28 Woodville Road
Woodville South SA 5011
Telephone: 08 8222 6841
Email: Health.CALHNResearchEthics@sa.gov.au

21 September 2016

Dr Elizabeth Murphy
Colorectal Surgery
Division of Surgery
Lyell McEwin Hospital
Elizabeth Vale SA 5112

Dear Dr Murphy,

Project title: Randomised controlled trial comparing intravenous fluids to no intravenous fluids during colonoscopy.

HREC reference number: HREC/15/TQEH/250

CALHN reference number: Q20151212

RE: Ethics Application APPROVAL

Thank you for submitting the above project for ethical and scientific review. The project was first considered by The Queen Elizabeth Hospital Human Research Ethics Committee (TQEH/LMH/MH) at its meeting held on 7 December 2015.

The HREC has reviewed all responses, and I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research, incorporating all updates*. The documents reviewed and approved include:

Document	*Version*	*Date*
Covering Letter	-	9 November 2015
NEAF Application:	AU/1/B76227	9 November 2015
Protocol: IV Fluids in Colonoscopy	3	18 September 2016
Participant Information Sheet and Consent Form: Person Giving Own Consent	2	1 September 2016
Patient Information Sheet, Covering letter	-	9 November 2015
Questionnaires: ○ Post Anaesthesia Recovery Score ○ Quality of Recovery Score ○ VAS	-	9 November 2015
GP Letter: IV Fluids in Colonoscopy	1	9 November 2015
Telephone Script	1	20 September 2016

Sites covered by this approval:

- **Lyell McEwin Hospital, SA: CPI – Dr Elizabeth Murphy**

HREC approval is valid for **5 years** from **21 September 2016 to 21 September 2021.**

Please quote the **HREC Reference number, HREC/15/TQEH/250** and the **CALHN Reference number, Q20151212** and allocated to your study on all future correspondence.

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

1. For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
2. This HREC is certified with the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review of Multi-Centre Clinical Trials. Any study sites that are not listed on this letter are not covered by this ethics approval. Any study-sites that wish to be added must contact the CPI, who must write formally to this HREC requesting the additional study site.

3. Adequate record-keeping must be maintained in accordance with GCP, NHMRC and state and national guidelines. The duration of record retention for all clinical research data is 15 years from the date of publication.
4. Researchers must notify the HREC of anything which might warrant review of ethical approval of the study, including:
   (a) serious or unexpected adverse effects on participants which warrant protocol change or notification to participants;
   (b) proposed changes in the study; and
   (c) premature termination of the study.
5. The HREC must be notified within 72 hours of any Serious Adverse Events occurring at any approved site.
6. Confidentiality of the research participants shall be maintained at all times as required by law.
7. Approval is valid for **5 years** from the date of this letter, after which an extension must be applied for.
8. Annual review reports must be submitted to the HREC, every 12-months on the anniversary of the above approval date. Each site covered by this HREC must submit a report, and it is the responsibility of the Coordinating Principal Investigator to ensure this is provided to the TQEH HREC Executive Officer, within 10 working days on each anniversary of the approval date, using the Annual Review Form available at: http://www.basilhetzelinstitute.com.au/research/information-for-researchers/human-research-ethics-committee/
9. The HREC must be advised with a final report or in writing, and a copy of any published material within 30 days of completion of the project.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained. For any queries, please contact the NALHN Governance Office: Healthnalhnrgo@sa.gov.au

This Committee is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research (2007)* incorporating all updates.

Should you have any queries about the HREC's consideration of your project, please contact Mrs Heather O'Dea, HREC Executive Officer on 08 8222 6841 or Health.CALHNResearchEthics@sa.gov.au

The HREC wishes you every success in your research.

Yours sincerely

Professor Richard E Ruffin
Chairman, Human Research Ethics Committee (TQEH/LMH/MH)

RR:HO

Cc: Alison Barr, NALHN RGO