



Ethics application approval

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a SA Health site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

08 September 2014

Dear Dr Reid

This is a formal correspondence from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188). This committee operates in accordance with the "National Statement on Ethical Conduct in Human Research (2007)." No hard copy correspondence will be issued.

Application Number: 183.14 - HREC/14/SAC/243

Title: Echo-guided fluid replacement in colonoscopy patients

Chief investigator: Dr. Peter Reid

Public health sites approved: Mount Gambier Hospital

The Issue: The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) have reviewed and approved the above application. The approval extends to the following documents/changes:

- SAC HREC general research application form v1.0 dated 26 May 2014
- Letter of support from Dr Jayaraman Thiagarajan, Head of Anaesthetics, Mt Gambier and District Health Services (no date)
- SA Health indemnity approval dated 26 April 2014

Your response to committee concerns received via email containing the following:

- Minute addressing committee concerns dated 05 September 2014
- Participant information sheet and consent form v1.1 dated 04 September 2014
- Email advising of the randomisation method dated 05 September

Approval Period: 08 September 2014 – 08 September 2017

Please read the terms and conditions of ethical approval below, as researchers have a significant responsibility to comply with reporting requirements and the other stated conditions.

For example, the implications of not providing annual reports and requesting an extension for research prior to approval expiring could lead to the suspension of the research, and has further serious consequences.

Please retain a copy of this approval for your records.

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Centre*

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TERMS AND CONDITIONS OF ETHICAL APPROVAL

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions.

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below.

Researchers have a significant responsibility to comply with the *National Statement 5.5* in providing the SAC HREC with the required information and reporting as detailed below:

1. **The approval only covers the science and ethics component of the application.** A SSA will need to be submitted and authorised before this research project can commence at any of the approved sites identified in the application.
2. **It is the policy of the SAC HREC not to provide signed hardcopy or signed electronic approval letters,** as our office is moving to electronic documentation. The SAC HREC office provides an unsigned electronic PDF version of the study approval letter to the Chief Investigator/Study Manager via email. These email approvals are generated via the email address research.ethics@health.sa.gov.au which can be linked back to the SAC HREC.
3. **If University personnel are involved in this project,** the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
4. **Compliance** with the *National Statement on Ethical Conduct in Human Research (2007)* & the *Australian Code for the Responsible Conduct of Research (2007)*.
5. To **immediately report to SAC HREC** anything that may change the ethical or scientific integrity of the project.
6. **Report Significant Adverse events (SAE's)** as per SAE requirements available at our website.
7. **Submit an annual report on each anniversary of the date of final approval** and in the correct template from the SAC HREC website.
8. **Confidentiality** of research participants **MUST** be maintained at all times.
9. A copy of the **signed consent form** must be given to the participant unless the project is an audit.
10. Any **reports or publications derived from the research** should be submitted to the Committee at the completion of the project.
11. All requests for **access to medical records** at any SAHS site must be accompanied by this approval email.
12. To **regularly review the SAC HREC website** and comply with all submission requirements, as they change from time to time.
13. The researchers agree to use **electronic format** for all correspondence with this department.

Kind Regards

Petrina Kasperski
Executive Officer

On behalf of
Professor David Gordon
Chair, SAC HREC