



01 June 2015

Dear Professor Mangoni

This is a formal correspondence from the Southern Adelaide Clinical Human Research Ethics Committee. Whilst this official title of the committee has changed the committee is still properly constituted under AHEC requirements with the registration number EC00188. This committee operates in accordance with the "National Statement on Ethical Conduct in Human Research (2007)." This department only uses email correspondence for all documents unless prior arrangements have been made with the manager. No hard copy correspondence will be issued.

Application Number: 76.14

Title: The relationship between methotrexate, blood pressure and arterial markers in rheumatoid arthritis

Chief Investigator: Professor Arduino Mangoni

Approved public health sites:

- Flinders Medical Centre
- Repatriation General Hospital

The Issue: The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) has approved the project amendment, and your project may now incorporate these amendments into your research. The approval extends to the following documents/changes:

- Cover letter
- SAC HREC Project Amendment Application form dated 05 May 2015
- Low Negligible Risk Application form v6 dated 05 May 2015
- Consent to Participation in Research v2 dated 01 April 2014 (tracked)

This amendment approval does not alter the current SAC HREC approval period for the study: 02 April 2016

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.

*Flinders Medical
Centre*

*The Flats G5 –
Rooms 3 and 4*

*Flinders Drive,
Bedford Park
SA 5042*

T: 08 8204 6453

*E: Research.ethics
@health.sa.gov.au*

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. **Compliance** with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
2. To **immediately report to SAC HREC** anything that may change the ethical or scientific integrity of the project.
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. **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.
5. **Report Significant Adverse events (SAE's)** as per SAE requirements available at our website.
6. **Submit an annual report on each anniversary of the date of final approval** and in the correct template from the SAC HREC website.
7. **Confidentiality** of research participants **MUST** be maintained at all times.
8. A copy of the **signed consent form** must be given to the participant unless the project is an audit.
9. Any **reports or publications derived from the research** should be submitted to the Committee at the completion of the project.
10. All requests for **access to medical records** at any SALHN site must be accompanied by this approval email.
11. To **regularly review the SAC HREC website** and comply with all submission requirements, as they change from time to time.
12. The researchers agree to use **electronic format** for all correspondence with this department.
13. Researchers are reminded that **all advertisements/flyers** need to be approved by the committee, and that no promotion of a study can commence until final ethics and executive approval has been obtained. In addition, all media contract should be coordinated through the FMC media unit.

Yours sincerely

Anna Pantelidis
Administration Officer, SAC HREC

On behalf of

Professor David Gordon
Chair, SAC HREC