



01 March 2012

Dear Professor Ramakrishna

This is a formal correspondence from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC). 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:** 079.12

**Title:** Development of new strategies to improve zinc status in children with environmental enteropathy at risk of diarrhea.

**Chief investigator:** Professor Ramakrishna

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

- Cover email dated 16 January 2012.
- Protocol "IRB revised submission
- Approval letter from CMC- IRB dated 26 November 2011.

**Approval Period: 01 March 2012 to 01 March 2015**

Please retain a copy of this approval for your records.

**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. **Report Significant Adverse events (SAE's)** as per SAE requirements available at our website.
4. **Submit an annual report on each anniversary of the date of final approval** and in the correct template from the SAC HREC website.
5. **Confidentiality** of research participants **MUST** be maintained at all times.
6. A copy of the **signed consent form** must be given to the participant unless the project is an audit.
7. Any **reports or publications derived from the research** should be submitted to the Committee at the completion of the project.
8. All requests for **access to medical records** at any SAHS site must be accompanied by this approval email.
9. To **regularly review the SAC HREC website** and comply with all submission requirements, as they change from time to time.
10. The researchers agree to use **electronic format** for all correspondence with this department.

*Flinders Medical  
Centre*

*Bedford Park  
SA 5042*

*Level 2*

*Room 2A221*

*Telephone*

*08 8204 4507*

*Facsimile*

*08 8204 4586*

Yours sincerely

Monika Malik  
Administration Officer  
SAC HREC