

Research Integrity

Human Research Ethics Committee

Wednesday, 23 April 2014

Dr Smita Shah

Western Clinical School: Medicine (Westmead); Sydney Medical School

Email: smita.shah@swahs.health.nsw.gov.au

Dear Smita

I am pleased to inform you that the University of Sydney Human Research Ethics Committee (HREC) has approved your project entitled "Application to analyse and report on SALSA outcome data for 2014/15".

Details of the approval are as follows:

Project No.: 2014/203

Approval Date: 23 April 2014

First Annual Report Due: 23 April 2015

Authorised Personnel: Shah Smita; Shrewsbury Vanessa; van der Sluijs Corinne; Andrew

Amy;

Documents Approved:

Date Uploaded	Туре	Document Name
10/03/2014	Recruitment Letter/Email	Appendix 2: Letter to Principal
4/04/2014	Questionnaires/Surveys	Revised evaluation questionnaire
4/04/2014	Participant Info Statement	Revised parent information letter

HREC approval is valid for four (4) years from the approval date stated in this letter and is granted pending the following conditions being met:

Special Condition/s of Approval

• It will be a condition of approval that permission is obtained from the NSW Department of Education (SERAP) and kept on file prior to research commencing.

Condition/s of Approval

- Continuing compliance with the National Statement on Ethical Conduct in Research Involving Humans.
- Provision of an annual report on this research to the Human Research Ethics Committee from the approval date and at the completion of the study. Failure to submit reports will result in withdrawal of ethics approval for the project.
- All serious and unexpected adverse events should be reported to the HREC within 72 hours.
- All unforeseen events that might affect continued ethical acceptability of the project should be reported to the HREC as soon as possible.



- Any changes to the project including changes to research personnel must be approved by the HREC before the research project can proceed.
- Note that for student research projects, a copy of this letter must be included in the candidate's thesis.

Chief Investigator / Supervisor's responsibilities:

- 1. You must retain copies of all signed Consent Forms (if applicable) and provide these to the HREC on request.
- 2. It is your responsibility to provide a copy of this letter to any internal/external granting agencies if requested.

Please do not hesitate to contact Research Integrity (Human Ethics) should you require further information or clarification.

Yours sincerely

Professor Glen Davis

Chair

Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.