

Research Integrity

Human Research Ethics Committee

Tuesday, 10 November 2015

Dr Alistair McEwan
Electrical Engineering; Faculty of Engineering and Information Technologies
Email: alistair.mcewan@sydney.edu.au

Dear Alistair

I am pleased to inform you that the University of Sydney Human Research Ethics Committee (HREC) has approved your project entitled “**Low cost body composition measurement for nutrition assessment using Near Infrared (NIR) light reflection from birth up to 2 years**”.

Details of the approval are as follows:

Project No.: 2015/595

Approval Date: 10 November 2015

First Annual Report Due: 10 November 2016

Authorised Personnel: McEwan Alistair; Norris Shane; Carberry Angela; Huvanandana Jacqueline; Jeffery Heather Elizabeth; Jones Peter; Mustafa Fatin;

Documents Approved:

| <u>Date</u> | <u>Type</u> | <u>Document</u> |
|-------------|----------------------------|---|
| 28/10/2015 | Study Protocol | Attachment 1_Research protocol_clean |
| 28/10/2015 | Participant Info Statement | Attachment 2_Patient information and consent form_clean |
| 28/10/2015 | Other Type | Attachment 4_Photo video release consent form |
| 25/09/2015 | Other Type | Attachment 7_PIS IAEA study |
| 25/09/2015 | Questionnaires/Surveys | Attachment 9_Infant Questionnaire_v2 |
| 25/09/2015 | Questionnaires/Surveys | Attachment 10_Infant questionnaire_third measurement |
| 25/09/2015 | Questionnaires/Surveys | Attachment 11_screening questionnaire_v2 |
| 25/09/2015 | Other Instruments/Tools | Attachment 12_Skin colour charts |
| 01/07/2015 | Questionnaires/Surveys | Protocol Attachment 2_parental questionnaire |
| 01/07/2015 | Other Type | Protocol Attachment 4_NIR SOP |
| 01/07/2015 | Other Type | Protocol Attachment 5_Deuterium Dilution SOP |

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



1. You will need to contact the University of Sydney Clinical Trials Governance Office to seek clearance prior to commencing.
2. You must register the trial with Australian New Zealand Clinical Trials Registry (ANZCTR): <http://www.anzctr.org.au/> and the South African National Clinical Trials Register www.sanctr.gov.za prior to commencing your study.

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.