



**HUMAN RESEARCH ETHICS
COMMITTEE (HREC)**

03-Dec-2014
Professor Valsamma Eapen
Sydney NSW 2052

Dear Professor Eapen,

HREC Ref: # **HC14267**

Study of an early intervention program for Autism Spectrum Disorders: Clinical outcomes and associated predictors to determine homogeneous sub-types

The Human Research Ethics Committee considered the above protocol at its meeting held on 02-Dec-2014 and is pleased to advise it is satisfied that this protocol meets the requirements as set out in the National Statement on Ethical Conduct in Human Research*. Having taken into account the advice of the Committee, the Deputy Vice-Chancellor (Research) has approved the project to proceed.

Would you please note:-

- approval is valid from 02-Dec-2014 to 01-Dec-2019;
- you will be required to provide annual reports on the study's progress to the HREC, as recommended by the National Statement;
- you are required to immediately report to the Ethics Secretariat anything which might warrant review of ethical approval of the protocol (National Statement 3.3.22, 5.5.7: <http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/e72.pdf>) including:
 - serious or unexpected outcomes experienced by research participants (using the Serious Adverse Event proforma on the University website at <http://research.unsw.edu.au/human-ethics-forms-and-proformas>);
 - proposed changes in the protocol; and
 - unforeseen events or new information (eg. from other studies) that might affect continued ethical acceptability of the project or may indicate the need for amendments to the protocol;
- any modifications to the project must have prior written approval and be ratified by any other relevant Human Research Ethics Committee, as appropriate;
- if there are implantable devices, the researcher must establish a system for tracking the participants with implantable devices for the lifetime of the device (with consent) and report any device incidents to the TGA;

- if the research project is discontinued before the expected date of completion, the researcher is required to inform the HREC and other relevant institutions (and where possible, research participants), giving reasons. For multi-site research, or where there has been multiple ethical review, the researcher must advise how this will be communicated before the research begins (National Statement 3.3.22, 5.5.7:
<http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/e72.pdf>);
- consent forms are to be retained within the archives of the PSYCH - School of Psychiatry and made available to the Committee upon request.

The committee is still to receive the working with children number for Valsamma Eapen

Sincerely,



Professor Heather Worth
Presiding Member
Human Research Ethics Committee

* <http://www.nhmrc.gov.au>