ABORIGINAL HEALTH
RESEARCH ETHICS COMMITTEE

8 December 2016

Principal Researcher (as per the AHREC application form):	Dr Deepa Jeyaseelan
Organisation:	Child Development Unit, Women's and Children's Hospital
Via email to the Principal Researcher and Corresponding Researchers:	Deepa.Jeyaseelan@sa.gov.au Kimberly.Johansen@sa.gov.au

RE: The ASQ-TRAK developmental screening tool for Australian Aboriginal children. Determining the reliability and face validity of the ASQ TRAK and exploring the characteristics of developmental difficulties in Aboriginal children in urban, regional and remote areas of South Australia
Ref. No: 04-16-702

Dear Deepa,
Thank you for your submission requesting ethical review from the Aboriginal Health Research Ethics Committee (AHREC).

I am pleased to inform you that the application was reviewed at AHREC's meeting held on 1 December 2016 and met with support. The Committee recommended your application for full approval with the following recommendations and standard conditions:

Recommendations

1) Staff members who administer the tool are proposed to scan and email the forms to the researchers – please be advised that this transfer should occur via secure encrypted channels.

2) The Committee advised that the forms and participant sheet should be presented in language especially given the scope of the study to collect data from different sites and to ensure that families clearly understand what their involvement means for them and their children.

3) Please be advised that ToysRUs is not accessible from or does not exist in most of the regional/remote areas. The Committee recommended the use of pre-purchased toys and books as an incentive.

4) The Committee recognises the logistics in standard procedures, however, recommended that the differences between the clinical and recruiter roles are made clear to potential participants in order to avoid coercion e.g. staff who will administer ASQ-TRAK to not be same the person as the one consenting the participant.

5) The Committee noted the information 'How your child acts with other people, how **she** behaves', it is recommended for the wording and utilised tools to be gender-specific.

6) The role and contributions of cultural consultants should be acknowledged as part of the study and an opportunity to co-author any publication should be offered.

7) Appropriate support and referral services should be made available to any parent who might experience distress due to an unexpected finding.

Standard Conditions

1) The approvals are granted based on the documentation and scope outlined by the researcher at the time of the review. AHREC must be notified of, and, approve, any changes to the study including minor or major changes to the study parameters, personnel updates and extension requests.

2) Where applicable, the onus of following the appropriate procedure for obtaining informed consent and protecting the well-being of a participant lies solely with researcher(s).

3) AHREC approvals are valid for 3 years from the date of the approval letter unless a maximum of 5 year approval timeframe is specifically requested, for example, in case of longitudinal studies and research projects conducted under Centres of Research Excellence. AHREC does not grant approvals indefinitely.

4) Studies aiming to involve an Aboriginal organisation, e.g. an Aboriginal Community Controlled Health Service, should adapt a partnership approach and go through a meaningful engagement process evidenced by an in-principle support letter or appropriate agreement.

    a. This letter or agreement should clearly articulate the time, expertise and resources required to support the study.
    b. Study timeframes and tools should be implemented with respect to the characteristics of each context engaged without an adverse impact on the quality of care and capacity of service.
    c. The Committee recognises that this process may not always be possible to finalise ahead of the ethical review process and advises that its approval is conditional upon the consultation process occurring to the satisfaction of the Aboriginal organisations and people whose support is sought to achieve study goals.

5) Where studies are granted approvals on the basis of the need to source ongoing advice from an established Aboriginal governance structure (e.g. Aboriginal advisory group, steering committee) or, where researchers indicated that it will be established, studies should be implemented as such. Should the ongoing monitoring of a study find that the original approval parameters were not adhered to by researchers, AHREC may further deliberate on the continued ethical acceptability of the study.

6) All adverse events to participants or local organisations and communities must be reported to AHREC immediately. These may include any serious or unexpected effect, unforeseen events and information that may invalidate the ethical integrity of the study.

7) Where possible, research participants should be supported for their time attending research activities. If the researchers will provide gift cards to incentivise participation, these should be basic cards that cannot be utilised for the purchase of alcohol or tobacco.

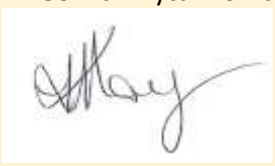
9 King William Road Unley SA 5061 PO Box 981 Unley SA 5061
Tel: (08) 8273 7200 Fax: (08) 8273 7299 Email: ahcsa@ahcsa.org.au Website: www.ahcsa.org.au

8) Research participants should be offered support for transportation to the location where research activities will take place and/or reimbursed for costs incurred e.g. parking, travel costs. This support should ideally be provided to participants up-front.

9) AHREC requires researchers to submit their annual reports every *1st of November* throughout the approval timeframe. Final reports can be submitted at any time. Please find the reporting template at: http://ahcsa.org.au/research-overview/ethical-review-ahrec/

We wish you well with the study and look forward to receiving your progress reports. If you require further information, please do not hesitate to contact the Executive Officer, Dr Gokhan Ayturk, on 08 8273 7200 or email Gokhan.Ayturk@ahcsa.org.au .

Sincerely yours,
Dr Gokhan Ayturk on behalf of



Kim Morey
Chairperson, AHREC