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23 August 2016

Dr Karen Hancock
Psychological Medicine
The Children's Hospital at Westmead

Dear Dr Hancock,

HREC Reference: HREC/16/SCHN/205

Project title: Effectiveness of school group-based acceptance and commitment therapy for children with anxiety: a randomised controlled trial

Sites: The Children's Hospital at Westmead

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Sydney Children's Hospitals Network Human Research Ethics Committee ("the Committee") at its meeting **22 July 2016** and subsequently the response to the request for further information was reviewed out of session on the **8 August 2016** and on the **22 August 2016**.

The HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review, and by the National Health and Medical Research Council as a certified committee in the review of multi-centre clinical research projects..

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the Committee has granted ethical approval of this research project. Your approval is valid for five (5) years, effective the date of this letter.

This application has been assessed in accordance with, and meets the requirements of the National Statement on Ethical Conduct in Human Research (2007).

The documents reviewed and approved by the Committee are:

Document	Version	Date
NEAF, Submission Code: AU/1/1637213		3 July 2016
Protocol	V2	28 July 2016

<i>Document</i>	<i>Version</i>	<i>Date</i>
Letter of Support from Queensland Cerebral Palsy & Rehabilitation Research Centre		25 May 2016
Parent information sheet ProACTIVE	V3	16 August 2016
Parent/Guardian Consent Form	V1	21 June 2016
Child information sheet ProACTIVE	V4	16 August 2016
Flyer advertisement for recruitment Parramatta diocese study	V2	28 July 2016
Child Anxiety Life Interference Scale (CALIS Child Version), © Centre for Emotional Health, Macquarie University		2013
Child Anxiety Life Interference Scale (CALIS Parent Version), © Centre for Emotional Health, Macquarie University		2013
CDI Short Questionnaire, © Multi-Health Systems Inc.		1999
Spence Children's Anxiety Scale (Child), © Susan H. Spence,		1994
Spence Children's Anxiety Scale (Parent), © Susan H. Spence,		2000
School Counsellor Questionnaire		Received 6 July 2016
Pediatric Anxiety Rating Scale (PARS)	V1.2	11 July 1997
Referral Form - Department Of Psychological Medicine	V2	28 July 2016
Response letter to HREC		Received 2 August 2016
School counsellor ProACTIVE questionnaire July 7 2016		Received 16 August 2016
Email cover letter		16 August 2016

Please note the following conditions of approval:

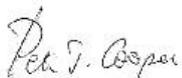
1. The Coordinating Investigator will immediately report anything which may warrant review of ethical approval of the project in accordance with the SCHN adverse event reporting policy.
2. All proposed changes to the research protocol, including the conduct of the research, changes to site or personnel, or an extension to HREC approval, are to be provided to the HREC or its delegate for review before those changes can take effect.
3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
4. The co-ordinating investigator will provide an annual report to the HREC on the anniversary of this approval letter, and a final report on completion of the study.
5. Your approval is valid for five (5) years from the date of the final approval letter. If your project extends beyond that five year period and you are still actively recruiting you will be required to resubmit your application incorporating any amendments within six (6) months of that approval expiry date. If your project is in follow up on, or analysis, please submit and application for amendment to extend the approval period. Ethics approval can be extended for a period of twelve (12) months at a time.
6. In the event of a project **not having commenced** within 12 months of its approval, the approval will lapse and reapplication to the HREC will be required.

Should you have any queries about the HREC's consideration of your project please contact the Ethics Administration Assistant on (02) 9845 1253.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The SCHN HREC wishes you every success in your research.

Yours faithfully



Dr Peter Cooper

**Chair, Sydney Children's Hospitals Network Human Research Ethics Committee
Sydney Children's Hospitals Network Human Research Ethics Committee**

NB: All clinical trials must now be registered on a publicly accessible registry such as the Australian New Zealand Clinical Trials Registry. For further information please go to www.anzctr.org.au. Please provide this office with a copy of your registration number for our records if you have not already done so.