

care, advocacy, research, education

Contact for this correspondence: <u>Research Ethics Office</u> Research Ethics Administration Assistant Phone: (02) 9845 1253 Facsimile: (02) 9845 1317 Email: <u>SCHN-ethics@health.nsw.gov.au</u> Corner Hawkesbury Road and Hainsworth Street Locked Bag 4001 Westmead NSW 2145 Sydney Australia DX 8213 Parramatta Tel +61 2 9845 0000 Fax +61 2 9845 3489 http://www.schn.health.nsw.gov.au/

ABN 53 188 579 090

15 November 2017

Ms Anita Gardner Psychologist, Psychological Medicine The Children's Hospital at Westmead

Dear Ms Gardner,

HREC Reference: HREC/17/SCHN/386

Project title: Westmead Feelings Program for adolescents with autism and mild intellectual disability

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 **20 October 2017** and subsequently out of session on the **13 November 2017**.

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
Adolescent questionnaire feedback Booster	Version 2	30 October 2017
Adolescent questionnaire feedback Module 1	Version 2	30 October 2017
Adolescent questionnaire feedback Module 2	Version 2	30 October 2017
Adolescent questionnaire feedback Module 3	Version 2	30 October 2017

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Document	Version	Date
Assessment ABAS-3 Ages 5-21 Parent Form		2015
Assessment ADOS-2 Module 3 - Child Adolescent		2012
Assessment ADOS-2 Module 4 - Adolescent Adult		2012
Assessment SRS - Parent Form		2005
Assessment WISC-V A&NZ		2014
Attendance Record Form	Version 1	5 September 2017
Background Information Questionnaire (Adol ASD Mild ID) self-report	Version 1	28 September 2017
Educator Consent Focus Group	Version 1	28 September 2017
Educator Information Sheet Focus Group	Version 3	13 November 2017
Friendship Questionnaire	Version 2	5 September 2017
HREA AU/1/9021311		28 September 2017
non-drug-device-protocol_WFP in Adol ASD	Version 3	30 October 2017
Parent Background Information Form	Version 1	5 September 2017
Parent information sheet Clinic Pilot	Version 2	30 October 2017
Parent information sheet Focus Group	Version 2	30 October 2017
Parent information sheet School pilot	Version 2	30 October 2017
Parent consent Clinic Pilot	Version 1	28 September 2017
Parent consent Focus Group	Version 1	28 September 2017
Parent Consent School Pilot	Version 1	28 September 2017
Parent Questionnaire 1	Version 3	31 October 2017
Parent Questionnaire 2	Version 3	31 October 2017
Principal Consent Form	Version 1	28 September 2017
Principal information sheet School Pilot	Version 2	30 October 2017
Professionals Consent Focus Group	Version 1	28 September 2017
Professional staff information sheet Focus Group	Version 2	30 October 2017
Questionnaire CBCL Parent	Version 1	17 March 2017
Questionnaire CBCL Teacher	Version 1	17 March 2017
Questionnaire DASS21	Version 1	12 April 2016
Questionnaire DBC Parent	Version 1	12 April 2016
Questionnaire DBC Teacher	Version 1	12 April 2016
Questionnaire EDQ Parent	Version 1	14 March 2017
Questionnaire EDQ Teacher	Version 1	14 March 2017
Questionnaire Emotion Regulation Checklist	Version 1	14 March 2017
Questionnaire SSIS Parent	Version 1	21 March 2017
Questionnaire SSIS Teacher	Version 1	17 March 2017
School Counsellor Consent School Pilot	Version 1	28 September 2017
School counsellor information sheet School Pilot	Version 2	30 October 2017

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Document	Version	Date
Student Background Information Form	Version 1	5 September 2017
Student Information Form School Counsellor	Version 2	5 September 2017
Student Information Form Teacher	Version 2	5 September 2017
Student Questionnaire	Version 1	14 March 2017
Teaching staff Consent Clinic Pilot	Version 1	28 September 2017
Teaching staff Consent School Pilot	Version 1	28 September 2017
Teacher information sheet Clinic Pilot	Version 2	30 October 2017
Teacher Questionnaire	Version 3	31 October 2017
Teacher Questionnaire 1	Version 2	31 October 2017
Teacher Questionnaire 2	Version 2	31 October 2017
Teaching staff information sheet School Pilot	Version 2	30 September 2017
Well-SEQ	Version 1	11 September 2017
HREC 17 SCHN 386 - Letter outlining changes made		13 November 2017
HREC.17.SCHN.386 - Reply to Ethic Review - 25 Oct 2017		8 November 2017

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 <u>annual</u> 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

SCarnett

Associate Professor Sarah Garnett 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 <u>www.anzctr.org.au</u>. Please provide this office with a copy of your registration number for our records if you have not already done so.