

care, advocacy, research, education

Contact for this correspondence:

Research Ethics Office

Research Ethics Support Officer

Phone: (02) 9845 1253 Facsimile: (02) 9845 1317

Email: SCHN-ethics@health.nsw.gov.au

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

24 November 2020

Dr Lauren Kelada Behavioural Sciences Unit Sydney Children's Hospital, Randwick

Dear Dr Kelada,

HREC Reference: 2020/ETH02598

Project title: SIBS-ONLINE: Community trial of an online program for

siblings and parents of children living with chronic

illness

Sites: Sydney Children's Hospital, Randwick

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 **9 November 2020** and subsequently by the Executive of SCHN HREC on the **23 November 2020**.

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
REGIS Project Registration	-	Received 29 Oct 2020
Letter of invitation to participant - Parents	V1	25 Sep 2020



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Document	Version	Date
Letter of invitation to participant - Siblings	V1	23 Oct 2020
Online advertisement	V1	25 Sep 2020
Participant resources - parents	V1	07 Sep 2020
Participant resources - young people	V1	07 Sep 2020
SIBS-ONLINE - phone call script	V1	01 Sep 2020
SIBS-ONLINE parent questionnaire1 pre	V1	25 Sep 2020
SIBS-ONLINE parent questionnaire2 post	V1	25 Sep 2020
SIBS-ONLINE parent questionnaire3 3m	V1	25 Sep 2020
SIBS-ONLINE sibling questionnaire1 pre	V1	25 Sep 2020
SIBS-ONLINE sibling questionnaire2 post	V1	25 Sep 2020
SIBS-ONLINE sibling questionnaire3 3m	V1	25 Sep 2020
HREA	V3	10 Nov 2020
PISCF-parents SIBS-ONLINE	V2	13 Nov 2020
PISCF-siblings over 18 SIBS-ONLINE	V2	13 Nov 2020
PISCF-siblings under 18 SIBS-ONLINE	V2	13 Nov 2020
Response to Committee Form	-	16 Nov 2020
SIBS-ONLINE - recruitment flyer	V2	16 Nov 2020
SIBS-ONLINE Protocol	V2	13 Nov 2020

## 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.
- 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.



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Should you have any queries about the HREC's consideration of your project please contact the Research Ethics Support Officer 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

Associate Professor Sarah Garnett

Sarah Gownett

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 <a href="https://www.anzctr.org.au">www.anzctr.org.au</a>. Please provide this office with a copy of your registration number for our records if you have not already done so.