

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

3 November 2020

Professor Claire Wakefield
Kids Cancer Centre
Sydney Children's Hospital, Randwick

Dear Prof. Wakefield,

HREC Reference: 2020/ETH02434

Project title: A novel multidisciplinary intervention to re-engage childhood brain cancer survivors

**Sites: Sydney Children's Hospital, Randwick
The Children's Hospital at Westmead
Perth Children's Hospital**

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 **16 October 2020** and subsequently by Executive of SCHN HREC on the **2 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Protocol	V1	11 Sept 2020

<i>Document</i>	<i>Version</i>	<i>Date</i>
Cover Letter	-	25 Sept 2020
PISC Survivor	V1	25 Sept 2020
Implementation Science, Interview Guide	V1	25 Sept 2020
Implementation Science, Invitation Letter- Health Professionals	V1	25 Sept 2020
Implementation Science, Invitation Letter, parent	V1	25 Sept 2020
Implementation Science , Invitation Letter- survivor	V1	25 Sept 2020
Implementation Science, PISC Parent	V1	25 Sept 2020
Implementation Science PISC Survivor	V1	25 Sept 2020
Invitation Letter, Parent	V1	25 Sept 2020
Invitation Letter, Survivor	V1	25 Sept 2020
Booster Session	V1	25 Sept 2020
Nurse consultation 2	V1	25 Sept 2020
Opt in Opt out card	V1	25 Sept 2020
Pre-notification of survey	V1	25 Sept 2020
Process Mapping guide	-	Rec'd 25 Sep 2020
Reminder of Survey	V1	25 Sept 2020
Social Media Posts	V1	25 Sept 2020
Treatment Summary	V1	25 Sept 2020
Video Invitation Script	-	25 Sept 2020
Western Australia Specific Module (WASM)	-	15 Sep 2020
REGIS Project Registration	-	Rec'd 25 Sep 2020
Health Assessment	V2	23 Oct 2020
HREA	V2	22 Oct 2020
Implementation Science, PISC Survivor	V2	23 Oct 2020
Nurse consultation 1	V2	23 Oct 2020
PISC Parent	V2	23 Oct 2020
Follow-Up Survey – 1 month	V2	23 Oct 2020
Follow-up survey- 6 months	V2	23 Oct 2020
Follow-Up Survey- 12 Months	V2	23 Oct 2020
Follow-Up Survey- 24 Months	V2	23 Oct 2020
Response to Committee Form (incorrectly dated 01 Oct 2020)		23 Oct 2020
Website information	V2	23 Oct 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.
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 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
Chair, Sydney Children's Hospitals Network Human Research Ethics Committee
Sydney Children's Hospitals Network Human Research Ethics Committee

CC Dr Jordana McLoone

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.