



**HUMAN RESEARCH ETHICS COMMITTEE**

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23 January 2017

A/Prof Claire Wakefield  
**Attention: Christina Signorelli**  
Sydney Children's Hospital - Kids Cancer Centre  
Level 1 High Street  
RANDWICK NSW 2031

Dear A/Prof Wakefield

**HREC ref no: 16/366 (LNR/16/POWH/695)**  
**Project title: Re-engaging the disengaged' in childhood cancer survivorship: A pilot study of a nurse-led, oncologist-supported, preventative program**

Thank you for submitting the above application for Low/Negligible Risk (LNR) ethical review. Based on the information you have provided and in accordance with the NHMRC guidelines [National Statement 2007 – Section 5 Institutional Responsibilities and “When does quality assurance in health care require independent ethical review?” (2003)], this project has been assessed as low risk and is therefore exempt from full HREC review.

Thank you for your correspondence dated **12 January 2016** responding to queries. The project was first considered by the LNR Committee on **06 December 2016**.

I am pleased to advise that ethical approval is granted for the following:

- LNR Form, AU/6/ED5A29 dated 24 Nov 2016
- Protocol, v1.1 dated 20 Dec 2016
- Intervention Manual, v1.1 dated 25 Nov 2016
- Invitation Letter, adult survivor, v1 dated 25 Nov 2016
- Invitation Letter, parent, v1 dated 25 Nov 2016
- Information sheet, adult survivor, v1.2 dated 11 Jan 2017
- Information sheet, parent, v1.2 dated 11 Jan 2017
- Consent form, v1.1 dated 20 Dec 2016
- Opt-in/out card, v1 dated 24 Nov 2016
- Baseline survey one, adult survivor, v1 dated 25 Nov 2016
- Baseline survey one, parent, v1 dated 25 Nov 2016
- Follow-up survey two, adult survivor, v1 dated 25 Nov 2016
- Follow-up survey two, parent, v1 dated 25 Nov 2016
- Follow-up survey three, adult survivor, v1 dated 25 Nov 2016

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- Follow-up survey three, parent, v1 dated 25 Nov 2016
- Follow-up survey four, adult survivor, v1 dated 25 Nov 2016
- Follow-up survey four, parent, v1 dated 25 Nov 2016
- Follow-up survey five, adult survivor, v1 dated 25 Nov 2016
- Follow-up survey five, parent, v1 dated 25 Nov 2016

The following document is acknowledged

- ANZCHOG endorsement letter dated 01 Aug 2016

Ethical approval is valid for the following site(s):

- Sydney Children's Hospital

Conditions of approval

1. This approval is valid for 5 years from the date of this letter.
2. Annual reports must be provided on the anniversary of approval.
3. A final report must be provided at the completion of the project.
4. Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the Committee.
5. The Principal Investigator will immediately report matters which might warrant review of ethical approval, including unforeseen events which might affect the ethical acceptability of the project and any complaints made by study participants.

**You are reminded that this letter constitutes ethical approval only. You must not commence this research project until you have submitted your Site Specific Assessment (SSA) to the Research Governance Officer of the appropriate institution and have received a letter of authorisation from the General Manager or Chief Executive of that institution.**

Should you have any queries, please contact the Research Support Office on (02) 9382 3587. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Research Support Office website: [www.seslhd.health.nsw.gov.au/POWH/researchsupport](http://www.seslhd.health.nsw.gov.au/POWH/researchsupport).

Please quote **16/366** in all correspondence.

We wish you every success in your research.

Yours sincerely

**Andrew Bohlken**

Executive Officer, Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*, NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.