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17 October 2018

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

Dear Prof Wakefield,

**HREC Reference: HREC/18/SCHN/186**

**Project title: Reboot Kids: a randomised controlled trial of a behavioural medicine intervention to prevent obesity and metabolic complications in young cancer survivors recently off treatment**

**Sites: Sydney Children's Hospital, Randwick  
Monash Hospital, Melbourne (Monash Health)  
Lady Cilento Children's Hospital, Brisbane  
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 **18 May 2018** and subsequently by the Executive of SCHN HREC on **27 August 2018** and out of session on the **17 October 2018**.

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>
Reboot Kids_RCT_Cover Letter		19 Apr 2018
HREA Submission code: AU/1/09B4318		08 Mar 2018
Reboot Kids_RCT_SAS System		Received 30 Apr 2018
3-Pass 24 Hour Dietary Recall Instructions_Vic Health	V1.0	30 Oct 2017
Answers to ethics queries		Received 23 Aug 2018
Answers to statistician queries		Received 23 Aug 2018
Email cover letter No.1		23 Aug 2018
Email cover letter No.2		23 Aug 2018
Email cover letter No.3		23 Aug 2018
FFQ questionnaire		Received 23 Aug 2018
Reboot Kids_Participant Information Sheet	V2	31 May 2018
Reboot Kids_RCT_Cover Letter		23 Aug 2018
Reboot Kids_RCT_Facilitator Intervention Manual	V2	30 May 2018
Reboot Kids_RCT_Parent Invitation Letter	V2	30 May 2018
Reboot Kids_RCT_Screen-time Questionnaire	V1	30 Oct 2017
Reboot Kids_RCT_T0 Survey	V2	30 May 2018
Reboot Kids_RCT_T1 Survey	V2	30 May 2018
Reboot Kids_RCT_T2 Survey	V2	30 May 2018
Victorian Specific Module		28 Feb 2018
Reboot Kids RCT Protocol V3	V1	02 Oct 2018
Reboot Kids_RCT_Cover Letter		16 Oct 2018
Reboot Kids_RCT_Screen Time Questionnaire	V2	12 Sep 2018
Email cover letter		16 Oct 2018

The documents noted by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Statistical endorsement (Dr Mark Donoghoe)		23 Aug 2018
RG151706_Agreement_UNSW signed copy of Agreement CCNSW PROGRAM GRANT		Nov 2015

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



Associate Professor Sarah Garnett  
**Chair, Sydney Children's Hospitals Network Human Research Ethics Committee**  
**Sydney Children's Hospitals Network Human Research Ethics Committee**  
CC Paayal Gohil

***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](http://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.***