*Reboot: A healthy habits program for young cancer survivors recently off treatment.*

**PARTICIPANT INFORMATION SHEET**

You are invited to participate in a research study to help us to evaluate a program called Reboot-KIDS, which aims to provide helpful facts and strategies for promoting healthy habits in young cancer survivors**.** The study is being conducted by Dr Jennifer Cohen from the University of New South Wales.

The Kids Cancer Centre is committed to improving our services by using feedback from families, patients, hospital staff, and other individuals involved in our projects. Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully.

**Study Investigators:**

Dr Lauren Winkler

School of Women’s and Children’s Health,

Faculty of Medicine,

University of New South Wales

**Telephone no:** 0412 331 225

Dr Jennifer Cohen

School of Women’s and Children’s Health,

Faculty of Medicine,

University of New South Wales

**Telephone no: 0405 153 595**

Prof Richard Cohn

Kids Cancer Centre

Sydney Children’s Hospital

**Telephone no: (02) 9382 1730**

Prof Claire Wakefield

Kids Cancer Centre

Sydney Children’s Hospital

**Telephone no: (02) 9382 3113**

### What is ‘Reboot KIDS’?

Cancer treatment can change children’s food preferences and eating habits. This can make healthy eating difficult, even after treatment has finished. Some parents report that cancer treatment changes the way they think about, and manage, their child’s eating. These changes can also continue after treatment. Reboot KIDS aims to help parents to understand the different ways that cancer treatment can affect children’s taste and food preferences. It also provides parents with helpful strategies to promote fruits and vegetables to young cancer survivors and evidence-based approaches to deal with fussy eating.

### What is the purpose of this study?

We would like to invite you to participate in a study to evaluate the impact of the Reboot KIDS program to promote healthy habits in young cancer survivors.

### ‘Why have I been invited to participate in this study?’

You are eligible to participate in this study because your child is aged between 2 and 12 years and has finished cancer treatment at the Kids Cancer Centre, Sydney Children’s Hospital.

### ‘What if I don’t want to take part in this study or if I want to withdraw later?’

Participation in this study is voluntary. If you decide not to participate, this will not affect the treatment you and your child receives at the Sydney Children’s Hospital Network in any way. If you wish to withdraw from the study once it has started, you can do so at any time without giving a reason. However, it may not be possible to withdraw your data from the study results if these have already had your identifying details removed.

### ‘What does this study involve?’

If you agree to participate in this study, you will be asked to:

* + Have a brief telephone conversation with the study coordinator to discuss the program in further detail and answer any questions you may have.
  + You will then be asked to complete the consent form and the computer access form
  + You will be asked at the beginning of your first intervention telephone call whether you consent to having all four intervention calls audio-recorded. This is to ensure that we deliver Reboot-KIDS consistently to all families and that the facilitator does not miss any important information.
  + There are two parts to this study – the program and the evaluation. Refer to “Study Flow Diagram” below.

### PART 1: The Reboot-KIDS program

Reboot KIDS has an initial module, and another 4 modules that are delivered fortnightly over 8 weeks. Each module will consist of a telephone consultation that will take 15 to 30 minutes followed by a web-based program that can be done at your own pace over the fortnight. The web-based program will take 30 to 45 minutes and has been split into core information and extra information to help cater for your available time. You can opt to do the telephone consultation via Webex, which will allow you to see the consultant. Consultations will provide brief education and skills-training and the web-based program will support what is discussed in the consultation. The following topics will be covered:-

* + - Information about how cancer can affect children’s eating habits and how parents approach their child’s eating
    - Recommended nutrition for children (based on current national guidelines)
    - Strategies to create a healthier environment and lessen screen time
    - Tips for encouraging children to more eat fruit and vegetables
    - Goal setting

All the tips and strategies we provide are only offered as suggestions. Parents can decide which strategies they might like to try.

During the Reboot web-based program, data will be collected to assist in personalising the program for you and to assist in evaluating the program.

### PART 2: Evaluation of the Reboot-KIDS program and collection of data

In order to take part in Reboot-KIDS you will need to complete surveys at three time points. Each survey should take about 30 minutes.

Information collected will be de-identified so your privacy is protected and will be stored on the Sydney Children’s Hospital secured research drive. Any hand recorded data will be de-identified and locked in drawers in the offices of the Kids Cancer Centre.

The evaluation component involves completing online surveys:

1. **Before the study:** These questions will ask a about your personal details and your child’s dietary intake and some aspects of your child’s home food environment, including your fruit and vegetable intake. In addition to the survey, we will also ask you to complete an online healthy cooking questionnaire, a screen time survey, and a ‘Three Pass 24 Hour Dietary Recall’ over the telephone. The dietary recall will be about what your child had to eat or drink on the previous day and will take 20 to 30 minutes.
2. **One week after Reboot KIDS module 4:** These questions will be identical to the ones you answered before you started the program, with the exception of the screen time survey and the healthy cooking questionnaire. In addition we will be asking for feedback on how useful you found the Reboot KIDS program. This will help us to understand what worked well and what we could do better.

**Six months after you have finished the study**:

These questions will be identical to the questions you completed before you started the study with the exception of the screen time survey and the healthy cooking questionnaire.

### ‘What if I don’t want my telephone calls audio- recorded’?

Audio-recoding is voluntary. You can still participate in the study even if you do not want your telephone calls audio-recorded. If you agree to audio-recoding, you will receive a hard copy of any telephone calls that we transcribe in the mail.

**Study Flow Diagram**



### ‘How is this study being paid for?’

The researchers will not receive personal payments for conducting this study. The study is funded by a Cancer Council NSW Program Grant.

### ‘Are there risks to me in taking part in this study?’

It is possible that thinking about your own or your child’s cancer experiences may cause you to feel worried or upset, however our experience has been that other parents who have completed the program have not become very upset and have instead found the program very helpful. Please be aware that the research team is available to talk about any worries or concerns you may have about participating in the study. You can contact the Trial Co-ordinator by calling the study telephone number: **1800-990-056**. If you are experiencing distress and need urgent help, please call your doctor or Lifeline on **13 11 14**. You may also find the resources listed at the end of this document helpful.

### ‘What happens if I suffer injury or complications as a result of the study?’

As this study does not involve the use of any medical procedure, there is very little likelihood that you will suffer any injury or complications as a result of this study.

### ‘Will I benefit from the study?’

This study aims to improve future treatment of nutrition related issues in young cancer survivors. We cannot guarantee you will receive any benefits however you might find the information and suggestions presented in the program helpful for you and your family.

### ‘Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything, nor will you be paid for your participation.

### ‘How will my confidentiality be protected?’

None of the people treating you or your child will know if you choose to participate in this study. Any data we collect will be de-identified. Your name will be replaced with a study identification number (Study ID). In order to mail out the study questionnaires and contact participants during the program, we will need participant’s name, address and telephone number. Only the study coordinator, will have access to these details which will be stored on a password protected word document on a locked computer in the offices of the Behavioural Sciences Unit, Kids Cancer Centre. This information will be permanently deleted once the study has finished. Electronic data will be saved on a password protected document on a locked computer drive, only accessible to the research team at the Kids Cancer Centre, Sydney Children’s Hospital. We do, however, need to keep the original consent forms, as required by law. These will be kept in a locked filing cabinet only accessible to the research team at the Kids Cancer Centre. As the consent form does not contain your study ID number, your name cannot be matched to the study ID number on your data. All information given will be stored for a minimum of 15years or until the youngest participants turns 25 (whichever is the longest).

### ‘What happens with the results?’

If you give us your permission by signing the consent document, we plan to publish the results in a peer- reviewed journal and present the results at domestic and international conferences. In any publication, information will be provided in such a way that you cannot be identified. If you would like to have a copy of the results, we can provide them to you as well. Overall results from the study may also be presented in newsletters sent from the Kids Cancer Centre at Sydney Children’s Hospital. You will not be able to be identified in the results we report.

### ‘What should I do if I want to discuss this study further before I decide?’

When you have read this information, the study coordinator, Dr Lauren Winkler will discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on 0412 331 225.

### ‘Who should I contact if I have concerns about the conduct of this study?’

This project has been approved by The Sydney Children’s Hospitals Network Human Research Ethics Committee (SCHN HREC). If you have any worries or questions about the study, please call the SCHN HREC Executive Officer (02 9845 3066). Please quote the study reference number: HREC/18/SCHN/186. You can send a letter to ‘Research Ethics’ at the Sydney Children’s Hospital Network, Locked Bag 4001, Westmead 2145, NSW, Australia.

**If you wish to take part, please return the consent form and computer access form in the reply paid envelope provided.** The study coordinator will then telephone you to answer questions you might have about the study and arrange access to the first survey.



**<Name of trial co-ordinator> / Telephone: <trial co-ordinator / Email: <trial co-ordinator>**

*Reboot KIDS: A healthy habits program for young cancer survivors recently off treatment.*

**CONSENT FORM**

1. I,................................................................................................................................................[name]

of ...............................................................................................................................................[address]

agree to participate in the study described in the participant information statement set out above.

1. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
2. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
3. I understand that I can withdraw from the study at any time without prejudice to my relationship to the Behavioural Sciences Unit, Sydney Children’s Hospital.
4. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
5. I understand that if I have any questions relating to my participation in this research, I may contact Study Coordinator, <name> on telephone < number>, who will be happy to answer them.
6. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.
7. I understand that audio recording of my telephone calls is voluntary.

### I consent to my telephone calls being audio recorded: YES NO

This project has been approved by The Sydney Children’s Hospitals Network Human Research Ethics Committee (SCHN HREC). If you have any worries or questions about the study, please call the SCHN HREC Executive Officer (02 9845 3066). Please quote the study reference number: HREC/18/SCHN/186. You can send a letter to ‘Research Ethics’ at the Sydney Children’s Hospital Network, Locked Bag 4001, Westmead 2145, NSW, Australia.

### Signature of parent Please PRINT name Date

\_

### Contact phone number: Preferred time of day to be contacted:

\_

### Signature of investigator Please PRINT name Date

\_

*Reboot KIDS: A healthy habits program for young cancer survivors recently off treatment.*

**COMPUTER ACCESS FORM**

1. Do you have access to a computer or an electronic device that allows you to access the internet in a private location?
   * Yes
   * No
2. If you indicated that you DO HAVE a computer or an electronic device with internet that you can access in a private space, does this computer or electronic device support or run a program like Skype?
   * Yes
   * No

*Reboot KIDS: A healthy habits program for young cancer survivors recently off treatment.*

**REVOCATION OF CONSENT**

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Behavioural Sciences Unit, Sydney Children’s Hospital.

### Signature of parent Please PRINT name Date

**PLEASE KEEP FOR YOUR RECORDS**

Should you decide you no longer wish to participate in this study; the section for Revocation of Consent should be forwarded to <name of trial co-ordinator>, Kids Cancer Centre, Sydney Children’s Hospital, High Street Randwick NSW 2031.

