Sydney Children’s Hospital

PARENT PARTICIPANT / INFORMATION SHEET AND CONSENT FORM

SIBS-ONLINE: Pilot of an online program for siblings and parents of children living with chronic illness

**Invitation**

You are invited to participate in a research study called SIBS-ONLINE. This study is aimed at finding out how useful online programs can be for improving the mental health of siblings of children with chronic ilness.

The study is being coordinated in Australia by the following researchers:

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| Name: | *Donna Drew* |
| Position: | *Clinical Nurse Consultant, Sydney Children’s Hospital* |
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The study is part of an international collaborative study coordinated jointly by Researchers in the following teams:

* Australian researchers at the Behavioural Sciences Unit, Kids Cancer Centre, Sydney Children’s Hospital, Australia
* Norwegian researchers from the Frambu Centre for rare disorders, Norway
* Norwegian researchers from the NKSE, Norway
* Norwegian researchers from the Department of Psychology at the University of Oslo, Norway and
* American researchers from the UC Davis Mind institute, US.

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 and discuss it with others if you wish.

1. **What is the purpose of this study?**

The purpose of this research is to evaluate the efficacy of the SIBS-ONLINE program at improving mental health for siblings of children with chronic illness. Siblings of children with chronic illness may be at a high risk for reduced wellbeing – the SIBS-ONLINE program thus aims to provide support for these siblings. This research is grounded in research on the specific needs of siblings of children with chronic illness and in research on the efficacy of online interventions for providing support to specific individuals.

1. **Why have I been invited to participate in this study?**

You have been invited because you have at least one child with a chronic illness and at least one child without a chronic illness. We are asking that both you and your ‘healthy’ child(ren) participate in this study.

1. **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. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you, UNSW Sydney, Sydney Children’s Hospital, the NKSE, the University of Oslo, or the UC Davis Mind institute.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. You can do this by returning a signed copy of the withdrawal of consent form to SIBS-ONLINE@unsw.edu.au

1. **What does this study involve?**

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

If you take part in the study, we will contact you directly about all matters relating to your and your child’s participation, if they are less than 18 years old. We will only contact your child (if they are less than 18) directly if given permission by you.

This study consists of an intervention conducted over the course of four weeks, and three brief questionnaires completed over the course of one year.

You require access to the internet in a private location (where you will feel comfortable discussing issues related to your child’s illness) once a week for four weeks, and a computer or tablet with a webcam and microphone to participate.

If you agree to participate in this study, you will be asked to participate in four weekly 90 minute group video-conference calls. The online sessions will be delivered online using video-conferencing software on the internet (e.g. Zoom, Skype) by two trained group leaders. These sessions will be delivered as a group with either other parents, or your child who is a sibling of a child with a chronic illness. Participants will be able to see and hear each other while communicating. Each session will include either psychoeducational content about knowledge of your child’s disorder, your emotional experiences, and family communication, or a discussion using these techniques.

You will also conduct two homework/feedback sessions with your child. These will be conducted using ‘break out rooms’ in the videoconferencing program so that you have privacy from the rest of the group, and so the group leader can drop-in on the conversation and provide guidance and feedback.

You will also be asked to complete three research questionnaires at different time points during the study: before the group sessions, immediately after the group sessions, and three months after the group sessions. These questionnaires should take 15-20 minutes each.

In addition, the researchers may access the medical record of your child with a chronic illness in order to obtain information relevant to the study. Information accessed in this manner will never be disclosed in an identifiable way to anyone outside of the study.

1. **Are there risks to me in taking part in this study?**

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:

Psychological Distress

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team.

Group Discussions

Whilst all care will be taken to maintain privacy and confidentiality, you may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting. To mitigate this, during the introductory session, participants will be briefed on the importance of confidentiality

There may also be risks associated with this trial that are presently unknown or unforeseeable.

If at any point during the study you feel distressed, you may contact the study coordinator at SIBS-ONLINE@unsw.edu.au. Additionally, Lifeline is a free 24-hour helpline that you can ring at 13 11 14*.* If it is an emergency, you can call 000.

1. **Will I benefit from the study?**

We cannot guarantee or promise that you will receive any benefits from this research; however, you may find it helpful to discuss your experiences. Sharing your experiences may also help other young people who have a brother or a sister with a chronic illness, and their families.

1. **Will taking part in this study cost me anything, and will I be paid?**

Participation in this study will not cost you anything. You will not be paid to participate.

1. **How will my confidentiality be protected?**

You do not need to share anything that you do not wish to discuss. Only the research staff in this study will know whether you have chosen to participate in this study.

Participant information and data will be held securely at Sydney Children’s Hospital Randwick and UNSW. All hard copy data will be locked in a filing cabinet, whilst electronic databases and information will be password protected and only accessible by the study team. At the completion of the research project, all identifying information will be removed from data sets. Any re-identifiable information will be confidentially disposed of 15 years (from publication) or after the youngest child participant turns 18. Ethical applications for any future research activities during this time will be applied for as necessary. Paper-based documents will be shredded, and all electronic files deleted, at the specified time.

The only time we will tell someone what you write in your questionnaires or say during your group sessions (except as required by law) is if we think you might have a severe emotional problem for which we think you are at risk. In this case we will tell your parent, who will do everything they can to make sure you are, and stay, safe. If you are not at risk, however, your parents will not know what you write in the questionnaires or say during your group sessions.

1. **What happens with the results?**

We plan to share the results with the ethics board, in peer-reviewed journals and at professional talks to promote knowledge in this field. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

1. **What should I do if I want to discuss this study further before I decide?**

When you have read this information, a researcher will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him/her at SIBS-ONLINE@unsw.edu.au.

1. **Who should I contact if I have concerns about the conduct of this study?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Sydney Children’s Hospitals Network (SCHN) HREC **(approval number: xxxxxxx)**.

If you have any concerns or complaints about any aspect of the project or the way it is being conducted, you may contact the Executive Officer of the SCHN HREC on (02) 9845 1253 or SCHN-Ethics@health.nsw.gov.au.

**Thank you for taking the time to consider this study.**

**If you wish to take part in it, please sign the attached consent form.**

**This information sheet is for you to keep.**

***Sydney Children’s Hospital***

## CONSENT FORM

[To be used in conjunction with a Participant Information Sheet]

**SIBS-ONLINE**

1. I,................................................................................................................. of................................................................................................................

agree to participate in the study described in the participant information statement set out above ***(or: attached to this form).***

2. 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.

3. 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.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to UNSW Sydney, the Sydney Children’s Hospital, the Frambu Centre for Rare Disorders, NKSE, the University of Oslo, or the UC Davis Mind institute.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Dr Lauren Kelada on +61 (2) 9382 3116 or at l.kelada@unsw.edu.au who will be happy to answer them.

1. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.
2. Please tick the box if you would like to receive a summary of results arising from this study [ ]

If you have any concerns or complaints about any aspect of the project or the way it is being conducted, you may contact the Executive Officer of the SCHN HREC on (02) 9845 1253 or SCHN-Ethics@health.nsw.gov.au.

# Signature of participant Please PRINT name Date

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**Signature of witness Please PRINT name Date**

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# Signature of investigator Please PRINT name Date

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**Sydney Children’s Hospital**

**SIBS-ONLINE**

## WITHDRAWAL 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 UNSW Sydney, the Sydney Children’s Hospital, the Frambu Centre for Rare Disorders, NKSE, the University of Oslo, or the UC Davis Mind institute.

# Signature of participant Please PRINT name Date

# [*or person responsible]*

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The section for Revocation of Consent should be forwarded to Dr Lauren Kelada at SIBS-ONLINE@unsw.edu.au