

## Participant Information Sheet – Parent/Guardian

<b>Title</b>	Supporting Children with Complex Feeding
<b>Short Title</b>	SuCCEED Study Group
<b>Protocol Number</b>	LNR/17/SCHN/340
<b>Project Sponsor</b>	SPHERE
<b>Coordinating Principal Investigator/ Principal Investigator</b>	Dr Christopher Elliot
<b>Associate Investigator(s)</b>	Ann Dadich, Nick Hopwood, Susan Woolfenden, Valsa Eapen
<b>Location</b>	SESLHD, SWSLHD, SCHN

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### Summary of Key Points:

- You are invited to be part of a project that aims to improve feeding clinic services and to enhance the support given to parents of children with feeding difficulties
- You do not have to participate if you do not wish to
- Even if you decide to participate, you can change your mind and withdraw at any time
- Your decision will not affect the support you receive from your local feeding clinic service

### Part 1 What does my participation involve?

#### 1 Introduction

This is an invitation for you to take part in this research project, called the Supporting Children with Complex Feeding Difficulties (SuCCEED) Study Group. You have been invited because you and your child are attending a feeding clinic service. The research project is aiming to enhance the support given to parents such as you by looking at existing feeding clinic practices and developing a new education package for parents. The child's contact details were obtained from feeding clinic records.

This Participant Information Sheet tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you do not wish to take part, you do not have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to taking part in the research project
- Consent to being involved in the research described
- Consent to the use your personal information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

## **2 What is the purpose of this research?**

The purpose of this research is to enhance support for parents of children with feeding difficulties. This is needed because parents have signalled that this support could be improved, and health professionals agree this is a priority to help get the best outcomes for children and minimise difficulty experienced by parents. It will fill gaps in knowledge relating to what parents think is most important to them, and how their needs can best be met. It will contribute to future care by developing a free online education package, and will inform future research by establishing a methodology for a larger scale study so the benefits can be spread.

We know that complex feeding difficulties are common and that parents' support for their children is crucial to their health and development outcomes. Research also tells us that parents don't always find it easy to care for themselves or their children in these circumstances, suggesting there is room for improvement in the support offered to them.

## **3 What does participation in this research involve?**

If you choose not to sign the consent form, no information will be collected about or from you whatsoever.

Participation in the study will involve one or more of the following, and the consent form you are given will show the specific options for you:

- Researchers video-recording part or all of one appointment at the feeding clinic service
- Participating in a one-hour focus group to share your experiences and help identify what needs to be improved
- Completing survey and screening tools about your experiences and feelings that help clinicians assess what support parents need
- Looking at a test version of a new online education package while a researcher sits with you and talks to you about what you think. You will be asked to tell the researcher what you like about it, and what you think should be changed.

If a video is taken of your appointment, it will not be shown in public or given to anyone outside the research team. Short parts of it may be shown to clinicians in this or other feeding clinics to help them spot good practices and areas for improvement. Short parts may also be shown in focus groups with other parents who attend participating feeding clinics and who are also participants in the study.

Your appointment at the feeding clinic will not be longer than usual, and the clinicians will not change the way they support you and your child, except by asking you to complete the survey/screening tools. These will take 15-30 minutes.

The session looking at the website will be audio recorded so researchers can match your comments to specific parts of the website.

The focus group will be no longer than 60 minutes.

The session looking at the test version of the website will take 30-60 minutes.

The study will be completed by July 2018.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study clinicians, university researchers or participants jumping to conclusions.

#### **4 Other relevant information about the research project**

There are no costs associated with participating in this research project, nor will you be paid. You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

#### **5 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your child's routine care, relationship with professional staff, or relationship with the hospital feeding clinic service.

#### **6 What are the possible benefits of taking part?**

There will be no clear benefit to you personally from your participation in this research. However, possible benefits may include learning from other parents in similar situations how they manage and what helps them, learning from the online education package, and positive feeling from being involved in a study that helps other families. We anticipate that other families will benefit because the professionals in participating feeding clinics will learn how to better support parents, and because the online education package will have information not currently provided to parents at these clinics, and it will have significant input from parents in its design.

#### **7 What are the possible risks and disadvantages of taking part?**

You may feel that some of the questions we ask are stressful or upsetting. You may be a bit anxious about having an appointment at the feeding clinic video recorded. If you become uncomfortable you can ask the video to be stopped at any time.

Filling out the survey / screening tools given to you by the professional may make you realise that things have been tough for you, perhaps tougher than you realised. Your usual clinicians will be able to suggest support you could access if you want it.

You may find that discussing your experiences, and hearing from others, in a focus group raises issues that are difficult or upsetting to talk about. You can leave the focus group at any time, and if you do get upset, the researchers will offer appropriate places where you can get support if you want it.

You may find that looking at the test online package makes you feel uncomfortable, for example when you hear or read stories from other parents. You can always stop the session at any time if you wish.

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.

## **8 What if I withdraw the child from this research project?**

If you do consent to participate, you may withdraw them at any time. If you decide to withdraw, please notify a member of the research team before withdrawal. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form (this will be provided to you by the research team).

If you decide to leave the research project, the researchers will not collect additional personal information, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time of withdrawal will form part of the research project results. If you do not want your data to be included, you must tell the researchers when withdrawing from the research project.

## **9 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as the participation of feeding clinics being withdrawn, or the investigators becoming unavailable.

## **10 What happens when the research project ends?**

At the end of the project, a report will be produced and shared with all participants. This will either be posted to you in hard copy, or sent via email, according to your preference.

The final project report will be written after all four elements are completed, and should receive the final report by the end of 2018.

## **Part 2 How is the research project being conducted?**

### **11 What will happen to information about me?**

By signing the consent form you consent to the research team collecting and using personal information about you for the research project.

The data that will be collected about you will include:

- Your name, and the basic details about your child's feeding as outlined above
- Notes made by the researchers while observing the clinic sessions and focus group sessions.

Any information obtained in connection with this research project that can identify you, including parent questionnaires, will remain confidential.

Video recordings of feeding clinic appointments will be kept on a password protected computer that can only be accessed by the research team. All parents and professionals participating in focus groups where short parts of the videos may be shown will sign forms indicating that they will treat everything they see confidentially. Any videos shown in focus groups will be edited to avoid confidential or sensitive information being made available (e.g. by cutting it out from excerpts shown, or blurring over names or particular information).

Recordings of focus groups and of parents using and commenting on the test online education package will only be seen by members of the research team and will be kept on a password protected computer.

Parent questionnaires will be securely stored by the research team.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the child cannot be identified, except with your express permission. Written publications will not mention any participants' real names. The online education package may include audio testimonials from parents and professionals that will be publicly available. No clips relating to you or your family will be used without written permission, and you can request that someone else's voice is used instead.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. In accordance with relevant Australian and/or New South Wales privacy laws, you have the right to request access to the information about the participant that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access the participant's information.

Any information obtained for the purpose of this research project and for the future research described that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

## **12 Complaints and compensation**

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

## **13 Who is organising and funding the research?**

This research project is being conducted by the Sydney Partnership in Health Education, Research and Enterprise (SPHERE).

The universities may benefit indirectly from publications other outputs that arise from this study, because these affect that money that universities get from the Australian Government.

The participant will not benefit financially from their involvement in this research project.



No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

#### 14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

The ethical aspects of this research project have been approved by the HREC of The University of Technology Sydney and the SCHN.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

#### 15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to involvement in the project, you can contact any of the following people:

##### Research contact person

Name	Dr Christopher Elliot
Position	Principal Investigator
Telephone	9113 1111
Email	Christopher.Elliot@health.nsw.gov.au

Name	Khadeejah (Kady) Moraby
Position	Project Officer
Telephone	9382 1021
Email	Khadeejah.moraby@health.nsw.gov.au

Name	Dr Ann Dadich
Position	Senior Lecturer
Telephone	9685 9475
Email	A.Dadich@westernsydney.edu.au

Name	Nick Hopwood
Position	Associate Professor
Email	Nick.Hopwood@uts.edu.au

Name	Associate Professor Susan Woolfenden
Position	Senior Staff Specialist Community / Developmental Paediatrician
Telephone	9382 8183
Email	Susan.Woolfenden@health.nsw.gov.au

Name	Professor Valsa Eapen
Position	Chair of Infant, Child & Adolescent Psychiatry Head, Academic Unit of Child Psychiatry, South West Sydney
Telephone	9616 4205
Email	V.Eapen@unsw.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

Name	Dr Christopher Elliot
Position	Principal Investigator
Telephone	9113 1111
Email	Christopher.Elliot@health.nsw.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

Reviewing HREC name	Sydney Children's Hospitals Network HREC
HREC Executive Officer	Associate Professor Sarah Garnett
Telephone	9845 1253
Email	SCHN-ethics@health.nsw.gov.au

**Local HREC Office contact**

The conduct of this study at Liverpool Hospital has been authorised by the South Western Sydney Local Health District, any person with concerns or complaints about the conduct of this study may also contact the Research Governance Office on (02) 8738 8304, email: [research.support@sswahs.nsw.gov.au](mailto:research.support@sswahs.nsw.gov.au) and quote project number 17/255.

# Form for Withdrawal of Participation – Parent/Guardian

**Title** Supporting Children with Complex Feeding Difficulties  
**Short Title** SuCCEED Study Group  
**Protocol Number** LNR/17/SCHN/340  
**Project Sponsor** SPHERE  
**Coordinating Principal Investigator/  
Principal Investigator** Dr Christopher Elliot  
**Associate Investigator(s)** Ann Dadich, Nick Hopwood, Susan Woolfenden,  
Valsa Eapen  
**Location** SESLHD, SWSLHD, SCHN

## **Declaration by Parent/Guardian**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my child's routine care or relationships with the researchers or hospital feeding clinic service.

Name of Parent/Guardian (please print) \_\_\_\_\_

Signature of Parent/Guardian \_\_\_\_\_ Date \_\_\_\_\_

In the event that the parent's/guardian's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

## **Declaration by Researcher<sup>†</sup>**

Name of Researcher (please print) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

<sup>†</sup> An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.