

## Participant Information

<b>HREC:</b>	HREC/2019/QGC/53657
<b>Project Title:</b>	<b>Oral feeding safety and aspiration risk in infants and children receiving high flow nasal cannula respiratory support.</b>
<b>Chief Investigator:</b>	<b>Dr Kelly Weir</b> , Conjoint Principal Research Fellow (Allied Health), Menzies Health Institute Queensland (Griffith University & Gold Coast Health), Allied Health Research, Level 2 Pathology & Education Building, Gold Coast University Hospital, 1 Hospital Boulevard, Southport QLD 4215 Telephone: 0448 042 484 <a href="mailto:kelly.weir@griffith.edu.au">kelly.weir@griffith.edu.au</a>
<b>Principal Investigator:</b>	<b>Dr Shane George</b> , Senior Staff Specialist Emergency Medicine & Children's Critical Care Unit, Department of Emergency Medicine & Children's Critical Care, Gold Coast University Hospital.
<b>Principal Investigator:</b>	<b>Professor Sheena Reilly</b> , Pro-Vice Chancellor – Health, Health Executive, Griffith University, Gold Coast Campus, Southport, QLD 4222
<b>Principal Investigator:</b>	<b>Professor Keith Grimwood</b> , Conjoint Professor of Infectious Diseases, Griffith University & Gold Coast Health, Griffith Health Building G40, Griffith University, Gold Coast campus, Southport, QLD 4222
<b>Principal Investigator:</b>	<b>Dr Susan Moloney</b> , Director of Paediatrics, Gold Coast University Hospital, Paediatric Outpatients, Ground Level, D Block, Gold Coast University Hospital, 1 Hospital Boulevard, Southport, QLD 4215
<b>Co-Investigator:</b>	<b>Dr Timothy Hong</b> , Staff Specialist Neonatology, Newborn Care Unit, Level 3, C Block, Gold Coast University Hospital, 1 Hospital Boulevard, Southport, QLD 4215
<b>Co-Investigator:</b>	<b>Dr Manbir Chauhan</b> , Staff Specialist Neonatology, Newborn Care Unit, Level 3, C Block, Gold Coast University Hospital, 1 Hospital Boulevard, Southport, QLD 4215
<b>Co-Investigator:</b>	<b>Angie Canning</b> , Senior Paediatric Speech Pathologist, Newborn Care Unit, C Block, Level 2, Gold Coast University Hospital, 1 Hospital Boulevard, Southport QLD 4215 Telephone: 0404 029 265, <a href="mailto:angie.canning@health.qld.gov.au">angie.canning@health.qld.gov.au</a>
<b>Co-Investigator:</b>	<b>Rachael Fairhurst</b> , Senior Paediatric Speech Pathologist, Newborn Care Unit, C Block, Level 2, Gold Coast University Hospital, 1 Hospital Boulevard, Southport QLD 4215
<b>Co-Investigator:</b>	<b>Professor Robert Ware</b> , Professor of Biostatistics, Menzies Health Institute Queensland, Griffith Health Building, G40_8.51, Griffith University, Gold Coast Campus, Southport, QLD 4222
<b>Co-Investigator:</b>	<b>Dr Thuy Frakking</b> , Research Manager Caboolture & Kilcoy Hospital & Health Service, Executive Centre, Building 3, Caboolture Hospital, Caboolture, QLD 4510

### Invitation to Participate in the Study

- You and your child are invited to participate in this research study.
- Please take your time to read this form carefully to understand the aim of the project and what it will involve.
- Please feel free to discuss this information with a family member, researcher, staff member or colleague.

### The Background and Aim of this Study

- Infants and children receive High Flow Nasal Cannula respiratory support to assist their breathing if their lungs are immature or if they have a respiratory disease such as bronchiolitis.
- High Flow Nasal Cannula, known as 'High Flow' or 'HFNC' is a type of respiratory support that delivers a warm, moist gas at high flow rates that generate positive airway pressure to a patient, generally through nasal cannula.
- Whilst on HFNC, children are usually given their food and fluid requirements via nasogastric tube feeding (a tube inserted into the child's nose to the stomach) due to concerns that the air pressures involved in HFNC will affect the child's ability to swallow safely. One concern is aspiration, where food and fluid go into the lungs during eating and drinking. This can make your child's respiratory condition worse and lead to lung problems.
- However, some hospitals are starting to allow children to feed orally (eat and drink by mouth) whilst on HFNC without determining whether this is a safe practice for children.
- This study aims to investigate whether it is 'safe' to eat and drinking by mouth while children are receiving HFNC (determine whether food or fluid goes into the stomach or windpipe/airway).

### What does my participation involve?

You and your child will be invited to be part of the study if your child is receiving HFNC to assist their breathing, is stable and has no other medical diagnoses which impact on their brain and swallow function, is aged between 35 weeks gestational age and 5 years of age, and your child's treating doctor is happy for your child to participate.

If you agree to have your child participate in the study, your child will be enrolled in the study.

A research speech pathologist will arrange a time to conduct a mealtime evaluation (clinical feeding evaluation). During the mealtime evaluation, we will tape a very small microphone on your child's neck to record swallowing and breathing sounds heard during eating and drinking. We will video your child's feeding or eating and drinking to analyse their oral motor and swallowing movements in sucking (if breast or bottle fed), spoon feeding, biting, chewing and swallowing (appropriate for your child's age); and listen to their swallow and breath sounds. The speech pathologist may make some recommendations based on the findings from the mealtime evaluation to improve your child's feeding safety and/or efficiency.

Following the mealtime evaluation, your child will be scheduled for a Videofluoroscopic Swallow Study (VFSS). A VFSS is a moving x-ray picture that shows how the muscles in the mouth and throat work during swallowing. The x-ray is conducted in the medical imaging department in the hospital with Radiology and Speech Pathology. During a VFSS a small amount of barium (a clear or white radio-opaque liquid or powder) is mixed with fluid/food. The barium helps to see the fluid/food clearly on the x-ray picture. The child is seated in their usual feeding position (or as close as possible to their usual feeding position) and is then given this fluid/food to drink/eat while recording the video x-ray.

During the video x-ray study, your child will again have the small microphone attached to the neck to record swallow and breath sounds.

If your child is an infant, a nurse and doctor will accompany you and your child to x-ray and stay for the procedure to ensure they are comfortable and their breathing (HFNC) support is OK.

If your child is older than one year of age, the nurse will usually accompany you and your child to monitor their breathing (HFNC) support. You may request a doctor to accompany your child if you wish.

Following this second study (VFSS – video x-ray), we will know if it is ‘safe’ – food and fluid going into the food pipe/oesophagus or whether some food/fluid goes into the windpipe/trachea and lungs (this is called ‘aspiration’). We will review the results with you in x-ray and advise your treating doctor. This information will then be discussed with you and your treating team, and your child’s care plan for mealtimes will be adjusted if required. If aspiration is observed the Speech Pathologist may recommend modifications to your child’s feeding plan such as changes to the feeding strategies, feeding equipment and fluid thickness/food textures.

### **Voluntary Participation**

- Taking part in this study is completely voluntary. You do not have to be involved if you don’t want to.
- You will not be paid any money for taking part in the study.
- You will be asked to sign a consent form prior to taking part in the study.
- If you decide to be part of the study, then change your mind, you are free to stop being part of the study at any time without having to give a reason.
- Your participation in the study will not impact on you or your child accessing services from the Gold Coast Hospital and Health Service.
- If you do not wish to consent to participate in the study your child will continue to be provided with standard care. This includes an assessment of your child’s feeding and swallowing by a speech pathologist, with recommendations such as a feeding plan. A VFSS will not typically be carried out (unless indicated) as a VFSS is not part of standard care.

### **Benefits and Risks**

- Participation in this research will include a videofluoroscopic swallow study (VFSS) which will expose your child to a small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and received a dose of 2 millisieverts (mSv) each year. The maximum additional effective dose from this study is 0.1mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal. (Research study: Radiation Dose and Risk Assessment, Biomedical Technology Services). This study is the ‘gold standard’ best diagnostic test that we have to assess for aspiration in children, and we use this diagnostic test routinely in the hospital for small children.
- Participating in this study may lead to researchers, speech pathologists, neonatologists, paediatricians and critical care doctors knowing about how to safely feed babies and children receiving high flow nasal cannula respiratory (HFNC) support.

### Feedback of Results

- If you wish to receive feedback about the results of this project, please feel free to ask the research speech pathologist or Dr Kelly Weir and we will send you a parent summary of the results at the end of the study via mail.
- The results of the research will be published in a peer-reviewed journal and may be presented to health professionals at a health conference for other health professionals to learn from our study.

### Confidentiality and Privacy

- When you give your consent for your child to participate in the study, your child will be issued a participant identification number. A master file of names and participant numbers will be kept separate from the data files. Forms with any identifying information will only be used as part of your child's clinical care and scanned to the medical record and then destroyed. All forms related to the study itself, will have your child de-identified and will use the participant identification number. All the evaluation sheets for children will only have their study participant identification number on the forms.
- No information which could identify you or your child as an individual will be published or given to the public, or other participants in the study.
- Relevant information related to your child's feeding will be included in your child's medical record for feeding management purposes only.

### Storage and Access to Information

- Completed paper copies of your child's results will be stored in a locked filing cabinet in Allied Health Research, Level 2 Pathology & Education Building, Gold Coast University Hospital, 1 Hospital Boulevard, Southport QLD 4215.
- Electronic data (e.g. databases, excel spreadsheets) will be saved as password protected files, in a folder on a research specific drive which only the study researchers can access.
- Following completion of the study and publication of research, the information will be kept for five years in accordance with the Australian National Health and Medical Research Council guidelines. After this time, all information (hard copies and electronic) will be securely destroyed according to standard Queensland Health procedures.
- As the Australian privacy laws state, you have a right to access information collected about you. Please contact one of the researchers if you would like to access your information.

### Questions or Further Information

- If you have any questions or concerns about this project, please contact the Principal Investigator Dr Kelly Weir via phone on 0448 042 484 (or email [kelly.weir@griffith.edu.au](mailto:kelly.weir@griffith.edu.au); [kelly.weir@health.qld.gov.au](mailto:kelly.weir@health.qld.gov.au)) or one of our research speech pathologists via phone on (07) 56873426 or email (Angie Canning [angie.canning@health.qld.gov.au](mailto:angie.canning@health.qld.gov.au) or Rachael Fairhurst [rachael.fairhurst@health.qld.gov.au](mailto:rachael.fairhurst@health.qld.gov.au))

### **Ethics Information**

- This project has been approved by the Human Research Ethics Committee of the Gold Coast Hospital and Health Service and will be carried out in accordance with the National Health and Medical Research Council of Australia.
- If you would like to speak to an officer not involved in the study, please contact the Gold Coast Hospital and Health Service Patient Liaison Office, Ms Wilma Sullivan on 07 5687 2048 or forward their concerns to the Chair, human Research Ethics Committee on 07 5687 3880.

### **Concerns or complaints**

Any concerns or complaints about the conduct of this study should be directed to the:

HREC Coordinator

Gold Coast University Hospital

1 Hospital Boulevard

SOUTHPORT QLD 4215

Email: [GCHEthics@health.qld.gov.au](mailto:GCHEthics@health.qld.gov.au)

Any complaint will be investigated promptly and you will be informed of the outcome.

**RESEARCH PARTICIPANT WITHDRAWAL OF CONSENT FORM**

**Study:** Oral feeding safety and aspiration risk in infants and children receiving high flow nasal cannula respiratory support.

**HREC No:** HREC/2019/QGC/53657

**Investigators:** Kelly Weir, Shane George, Sheena Reilly, Keith Grimwood, Susan Moloney, Timothy Hong, Manbir Chauhan, Angie Canning, Rachael Fairhurst, Robert Ware & Thuy Frakking.

You can withdraw your participation consent by advising the researcher, Kelly Weir, verbally, via email to or by returning this completed form to:

**Dr Kelly Weir**

Conjoint Principal Research Fellow (Allied Health),  
Menzies Health Institute Queensland (Griffith University & Gold Coast Health),  
Allied Health Research, Level 2 Pathology & Education Building,  
Gold Coast University Hospital,  
1 Hospital Boulevard, Southport QLD 4215  
Telephone: 0448 042 484  
[kelly.weir@griffith.edu.au](mailto:kelly.weir@griffith.edu.au)   [kelly.weir@health.qld.gov.au](mailto:kelly.weir@health.qld.gov.au)

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Gold Coast Hospital and Health Service or Queensland Health.

Name of participant \_\_\_\_\_

Date: \_\_\_\_\_

Signature of  
participant \_\_\_\_\_

## Participant Consent Form

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<b>Chief Investigator:</b>	<b>Dr Kelly Weir</b> , Conjoint Principal Research Fellow (Allied Health), Menzies Health Institute Queensland (Griffith University & Gold Coast Health), Allied Health Research, Level 2 Pathology & Education Building, Gold Coast University Hospital, 1 Hospital Boulevard, Southport QLD 4215 Telephone: 0448 042 484 <a href="mailto:kelly.weir@griffith.edu.au">kelly.weir@griffith.edu.au</a>
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<b>Principal Investigator:</b>	<b>Professor Sheena Reilly</b> , Pro-Vice Chancellor – Health, Health Executive, Griffith University, Gold Coast Campus, Southport, QLD 4222
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<b>Co-Investigator:</b>	<b>Dr Thuy Fracking</b> , Research Manager Caboolture & Kilcoy Hospital & Health Service, Executive Centre, Building 3, Caboolture Hospital, Caboolture, QLD 4510

I, \_\_\_\_\_ (please print name in full), the parent / legal guardian of \_\_\_\_\_ (please print your child’s name in full), date of birth \_\_\_\_ / \_\_\_\_ / \_\_\_\_ (please provide your child’s date of birth) agree to participate in the research study entitled “**Oral feeding safety and aspiration risk in infants and children receiving high flow nasal cannula respiratory support**” and acknowledge that:

- I have read the information sheet and understand the purpose of this study.
- Any questions that I have, have been answered to my satisfaction.
- I have been informed of and understand any possible risks to my and my child’s health or well-being.
- I have been informed that the confidentiality of my information will be maintained and safeguarded as per Queensland Health standards.
- I understand that I will not be paid for my participation in this project.
- I am aware that the project may or may not result in any direct benefit to me or my child.
- I understand that my participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, and without affecting the service that I receive from the Gold Coast Hospital and Health Service.
- I have been advised that the Executive Director, Gold Coast Hospital and Health Service, on recommendation from the Gold Coast Hospital and Health Service Human Research Ethics Committee has given approval for this project to proceed.

Child’s Name: .....

Parent/Guardian’s Name: ..... Signature: .....

Name of Investigator: ..... Signature: .....