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High-Flow for Paediatric Airway Surgery

Appendix I

(Local Site Logo)

(Affix patient identification label here)	
URN:	
Family Name:	
Given Names:	
Address:	
Date of Birth:	Sex: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> I

PARENT/GUARDIAN CONSENT FORM

Project Title High-flow Nasal Oxygen for Children's Airway Surgery
HREC Number HREC/18/QRCH/130
Investigator Dr Susan Humphreys [*Local site investigator(s)*], Ms Tara Williams
Version: Version 2: 01.03.2019

Thank you for taking the time to read this [Parent/Guardian Information Statement and Consent Form](#). We would like to ask you and your child to participate in the High-flow Nasal Oxygen for Children's Airway Surgery research project that is explained below and it's ok to say no if you do not want to be a part of this study.

What is an Information Statement?

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether or not you would like your child to take part in the research. Please read this Information Statement carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Important things to know

- It is your choice whether or not your child takes part in the research. You do not have to agree if you do not want to.
- If you decide you do not want your child to take part, it will not affect the treatment and care your child receives through [*Local Hospital Name*]

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If you would like your child to take part in the research project, please sign the consent form provided by the Researcher. By signing the consent form, you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to your child taking part in the project

We will give you a copy of this information and consent form to keep.

1. What is the research project about?

The aim of this project is to compare two techniques for delivering oxygen during anaesthesia for children requiring airway procedures. Infants and children with an airway abnormality often require surgery of their upper airway to improve their breathing. During airway surgery, maximising oxygen delivery is a very important aspect of anaesthesia as we know children undergoing airway procedures may experience low oxygen levels during their procedure. These are managed by interrupting the procedure and increasing the oxygen to the child; often by taking over their breathing or/and placing an artificial breathing tube to deliver the oxygen. Interrupting the procedure may prolong the overall procedure and anaesthesia time. Traditionally, the anaesthesia technique has involved delivery of low flow oxygen (Low-Flow) via an oxygen catheter tube placed in the nose. Our research team have been investigating the use of a newer mode of oxygenation for children undergoing anaesthesia called 'High-Flow Nasal Oxygen' (High-Flow). In High-Flow, warm and humidified oxygen is delivered to the airway via nasal cannulae. For this study half (50%) of the children will receive low-flow oxygen during their procedure and the other half (50%) will receive high-flow oxygen during their procedure. The chance is 50% like tossing a coin. Your child will be carefully monitored and cared for as per normal procedure during the procedure.

The aim of our research is to compare these two methods of oxygen delivery in paediatric airway surgery. The results of this study may change current practice and improve the safety of our children during these procedures in our hospitals.

2. Who is funding the research project?

This study has not received funding. However, the study has been supported by Fisher and Paykel in providing the necessary equipment.

3. What if I wish to withdraw from the research project?

If you decide for your child to participate, you are free to withdraw your consent and to discontinue participation at any time. Your decision regarding whether or not your child participates in the study

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will not prejudice their future relations with *[Local Hospital Name]*. If you decide your child may participate, you are free to withdraw consent and discontinue participation at any time. The decision to withdraw from the study will not affect your child's routine medical treatment or their relationship with the people treating them.

4. What are the possible benefits for my child and other people in the future?

This study may not have any direct benefits for your child; however, it will help us gain more of an understanding of which of the oxygenation techniques is better for anaesthesia in children requiring airway surgery.

5. What are the possible risks, side-effects, discomforts and/or inconveniences?

The risks associated with general anaesthesia have already been discussed with you during the anaesthetic assessment. There are no further risks associated with taking part in this study. High-flow therapy is an established form of breathing support for children with respiratory illnesses and abnormal airways during anaesthesia. The nasal prongs used for the high-flow therapy treatment are similar to those we would use for standard nasal oxygen delivery. Your child will be anaesthetised and unaware of the oxygen delivery device used and this is removed immediately at the end of the procedure. An extra monitoring probe will be placed on your child skin during their procedure which will not cause any harm or discomfort to you child and will be removed before they wake up.

6. What will be done to make sure my child's information is confidential?

Confidentiality of your data will be maintained. All identifying material will be de-identified for collation and analysis. Paper forms will be held securely in a locked location at *[Local Hospital Name]* site, and may be accessed by our ethics committee, auditors or regulatory authorities. This study is occurring at various hospitals around Australia co-ordinated by the Paediatric Critical Care Research team at Children's Health Queensland Hospital and Health Service. De-identified data collected at this site is electronically transferred and stored securely at the University of Queensland. Your child's privacy will be maintained at all times. Your child's name will not be used in any presentations or publications of the study results.

7. Who should I contact for more information?

If you would like more information about the project or if you need to speak to a member of the research team in an emergency, please contact:

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Name	Position	Phone	Email
XXXX	XXXX	XXX	XXXX
Tara Williams	Study Co-ordinator	07 3068 1474	CHQ_PCCRG_Research@health.qld.gov.au

HREC Information:

The Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC) has approved this study. If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact the HREC Co-Ordinator on:

3069 7002 or email CHQETHICS@health.qld.gov.au

Thank you for your time and consideration of participation in this study.

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Title High flow nasal oxygen for children's airway surgery

Principal Investigator Dr Susan Humphreys
[Local site investigator(s)]

Declaration by Parent/Guardian

I have read the Parent/Guardian Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to my child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Child (please print)	_____
Signature of Child	_____
<i>(Optional: remove if not required)</i>	Date _____
Name of Parent/Guardian (please print)	_____
Signature of Parent/Guardian	_____
	Date _____

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Declaration by Study Doctor / Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent/guardian has understood that explanation.

Name of Study Doctor/ Senior Researcher [†] (please print)	
Signature _____	Date _____

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