**Participant Information Sheet/Consent Form**

**Interventional Study** -*Parent/Guardian consenting on behalf of participant*

An **Interventional Study** is defined as administration of a drug, device or procedure that is not part of routine care, including all phases of a clinical trial.

A Participant Information sheet should be aimed at parents/guardians when the potential participant is a child. Refer to *The National Statement on Ethical Conduct in Human Research* (Chapter 4.2) for more information. Consideration should also be given to explaining the procedure to the child themselves in a manner appropriate to their maturity level.

**Instructions for Creating a** **Participant Information Sheet/Consent Form**

⮞ **This template is a guide only.**

⮞ For projects that do not involve trialling a clinical drug, procedure or device, one of the other participant information and consent form templates should be used.

⮞ If more than one Participant Information Sheet/Consent Form is required for your research project, please label the different forms clearly for the different participant groups. Please note that if there is a sub-study, a separate form is required.

⮞ There are 20 numbered sections in this template. Please ensure that all relevant sections are included and numbered appropriately in your final document. These headings are included to ensure that all the National Statement and ICH/GCP elements are addressed.

⮞ You should delete any headings and sections that are not relevant to your study and/or modify paragraphs so that they are relevant to your study.

⮞ In this template, there are prompts for the content of your Participant Information Sheet/Consent Form (in *orange italics*) and instructions regarding the format of your document (in *blue italics*). Please ensure that you delete all prompts (*orange italics*) and instructions (*blue italics*) from the final document.

⮞ **Preferred language** recommendations for use in your Participant Information Sheet are in black text with a border around paragraphs. Ensure that the border is removed from the ‘Preferred language’ sections in the final document. Note that this formatting does not apply to section 20 or to the Consent Form.

⮞ If institutional letterhead/logo is to be used, leave space for the letterhead/logo in accordance with the institution’s requirements.

⮞ Include the version date of the document in the footer of each page. Do not use the ‘automatic’ date insertion function (see over).

⮞ Use the ‘1 of X’ pagination option. Ensure that all references to version date or pagination in the text are correct and consistent with the information in the footer (see over).

⮞ Do not include a place for initialling the document on each page.

⮞ Study participants should be referred to as ‘participants’ and not ‘subjects’ or ‘patients’.

⮞ References to the National Statement (NS) and ICH/GCP Guidelines are noted in relevant sections as footnotes for your information only and do not need to be included in the final document.

⮞ This guide proposes preferred language for some sections of the Participant Information Sheet/Consent Form. This preferred language may be the totality of what is required for the section or it may be a series of suggested phrases to be used along with other information in the section, as indicated by the guidelines pertaining to the section.

⮞ The reviewing institution may have additional preferred language or standard clauses that you are required to include. Please check with the relevant HREC administration to determine whether additional requirements apply.

⮞ Language used should be readily understandable by the parent/guardian (Grade 8 reading level or below) and include Australian spelling of words.

⮞ If translated Participant Information Sheet/Consent Forms are to be used, please check with the relevant HREC administration in case additional requirements apply.

⮞ You should state whether an interpreter will be used in the consent process and/or during the collection of data.

⮞ Text should be at least font size 11 in an easily readable font style.

⮞ Ensure that all font styles and sizes, bolding, italicisation and underlining are intended and that any variations are consistent throughout the document.

⮞ **Please ensure that your final document is proofread.**

 This space is reserved for use by jurisdictions or institutions for instructions regarding version control of Participant Information and Consent Forms or other matters specific to jurisdictions or institutions.

University of New South Wales (UNSW)

**Participant Information Sheet/Consent Form – Parent/Guardian**

**Interventional Study** -*Parent/Guardian consenting on behalf of participant*

Albury Base Hospital



**Part 1 What does the child’s participation involve?**

**1 Introduction**

This is an invitation for the child in your care to take part in this research project because they are undergoing a tonsillectomy. The research project is testing whether the time of laryngeal mask airway removal has an impact on emergency delirium.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want the child 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 the child can take part, you might want to talk about it with a relative, friend or the child’s local doctor.

Participation in this research is voluntary. If you do not wish the child to take part, they do not have to. The child will receive the best possible care whether or not they take part.

If you decide you want the child 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 the child taking part in the research project

• Consent for the child to have the tests and treatments that are described

• Consent to the use of the child’s personal and health 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?**

Emergence delirium refers to agitation after waking up from general anaesthesia. It is a common problem in children, occurring in up to 80% of them. Our aim is to identify whether we can minimise this occurrence by removing the specific type of airway device used in the majority of tonsil removal surgeries at Albury Wodonga Health at a particular time during the procedure. Knowing this may pave the way for further research in this area, as well as improvements in clinical practice.

The results of this research will be used by the student, *Dhruv Kapoor,* to obtain a Bachelor of Medical Studies/Doctor of Medicinedegree.

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

The child will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

You (the parent or carer) will be required to sign a consent form before any study assessments are performed.

One of the research team will assess your child’s suitability for the study. This will require:

1. Your child to be aged 2-7 years, and undergoing surgical removal of their tonsils.
2. Successful placement of a laryngeal mask airway during their anaesthesia

Your child will be excluded from the study if:

1. They have a known or suspected difficult airway
2. The laryngeal mask airway cannot be inserted and an alternate airway device is required
3. The anaesthetist is concerned for any medical reason
4. The parents are unable to speak English

We will be collecting some information about the child such as their age, gender, weight and regular medications before the surgery. Then the student will gather information such as Paediatric Anaesthesia Emergence Delirium score after the surgery is complete in the post anaesthesia care unit 5 and 20 minutes after eye opening.

Study procedure

Children will be checked whether they are able to participate in the study on admission to the children’s ward or day surgery unit before the surgery. Consent will be gained from the parents. Once consent has been obtained, a starting score will be gathered, and the children will be randomly put into two different groups. The groups will differ only in the timing of the removal of the laryngeal mask airway at the end of the surgery. In one group the laryngeal mask airway will be removed in the theatre where the surgery is performed, and in the other group the laryngeal mask airway will be removed in the recovery room (post-anaesthesia care unit). This will be the only change to the routine care that your child will receive.

The anaesthetist in charge will determine what drugs the child needs. If the laryngeal mask airway is not able to be successfully inserted, then the anaesthetist will place a different kind of breathing tube and the child will exit the study but the surgery will continue as normal.

Once the surgery is complete, normal breathing will be confirmed. The anaesthetist will remain with the child until handover to the post anaesthesia care unit. Any unwanted effects like breathing difficulties will be managed in the usual way by the doctors and nurses in charge.

As your child wakes, the research student will collect Paediatric Anesthesia Emergence Delirium scores at 5 and 20 minutes after the child opens their eyes.

There are no additional costs associated with participation in this research project, nor will you or the participant be paid. All medication, tests and medical care required as part of the research project will be provided to the child free of charge.

**4 What does the child have to do?**

The parents of the child must give consent before being included in the study and be willing to have the student observe the child after the surgery. If the child or parents can remember any medications taken before the surgery, then please tell the student. Other than that, the child continues with the surgery as per normal

**5 Other relevant information about the research project**

This study involves Albury Wodonga Health and the University of New South Wales. Data will be collected at Albury Wodonga Health-Albury Campus.

**6 Does the child have to take part in this research project?**

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

If you do decide that the child can 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 that the child can or cannot take part, or that they can take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them, or their relationship with UNSW

**7 What are the alternatives to participation?**

The child does not have to take part in this research project to receive treatment at this hospital.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that the child will receive immediate benefits from this research; however, their participation will yield results that might benefit children who undergo a tonsillectomy in the future. Also, their participation may spark ideas for further students to research in this area.

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

The patient will be at no risk of harm from the observation process of this research. Any risks, complications or side effects from the tonsillectomy procedure will be managed by the medical staff undertaking the anaesthesia and surgery.

These days, whilst anaesthesia is very safe, there are some risks associated with it. Common problems associated with anaesthesia are feeling unwell or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most patients do not have these problems. If these problems do happen, they usually get better very quickly. Damage to teeth may occur, but this is rare. The risk of major complications related to the heart, lungs or brain, or death due to anaesthesia is very rare. These risks will be discussed with you by your treating anaesthetist as a routine part of the pre-anaesthetic assessment.

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the student or supervisor will tell you about it and discuss with you whether you want your child to continue in the research project. If you decide to withdraw your child, the student or supervisor will make arrangements for their regular health care to continue. If you decide that the child can continue in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, the student or supervisor might consider it to be in the child’s best interests to withdraw them from the research project. If this happens, the student or supervisor will explain the reasons and arrange for the child’s regular health care to continue.

**12 Can the child have other treatments during this research project?**

The child can continue with any medical treatments they are receiving. This information will be noted by the researcher prior to the surgery.

It may also be necessary for the child to take medication during or after the surgical procedure to address side effects or symptoms that they may have. You may need to pay for these medications and so it is important that you ask the surgeon or doctor in charge about this possibility.

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

If you decide to withdraw the child from the project, please notify a member of the research team before you withdraw them. This notice will allow that person or the research supervisor to remove the participant from the data collection. If the participant wishes to remove themselves from the study during the study, then their information will be removed.

**14 Could this research project be stopped unexpectedly?**

Due to the current environment with COVID-19, the project at any time, at the discretion of UNSW, can be temporarily postponed or adjusted to minimise patient contact.

**15 What happens when the research project ends?**

The results of the research project will not be sent to participants but should the participants request a copy of the results or the project, then it may be made available to them. It is intended that the results will be published in a journal and/or presented at a medical conference.

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

**16 What will happen to information about the child?**

The information will be stored on a password protected computer, and accessible only to investigators involved in the study. It will be kept in accordance with NHMRC guidelines and then destroyed. The data will be non-identifiable. The child’s 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.

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.

In accordance with relevant Australian and NSWprivacy and other relevant laws, you have the right to request access to the participant’s information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study 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 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.

**17 Complaints**

Should the child suffer any complications or injuries from the surgery then the surgical team and discharge staff will assist the child. Should the parents of the child or child themselves wish that the student no longer observe them for the purposes of the study, then they can raise the issue with the student and the student will remove them from the study.

**18 Who is organising and funding the research?**

This research project is being conducted by a UNSW student with Dr. Luke Baitch as the supervisor. No funding will be received for the research.

**19 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 Albury Wodonga Health.

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.

**20 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 the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study personnel below:

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | *Dhruv Kapoor* |
| Position | *Student* |
| Telephone | *0470441242* |
| Email | *dhruv199917@gmail.com* |

|  |  |
| --- | --- |
| Name | *Dr Luke Baitch* |
| Position | *Supervisor* |
| Telephone | *0406586318* |
| Email | *luke.baitch@optusnet.com.au* |

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

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *Dhruv Kapoor* |
| Position | *Student* |
| Telephone | *0470441242* |
| Email | *dhruv199917@gmail.com* |

|  |  |
| --- | --- |
| Name | *Dr Luke Baitch* |
| Position | *Supervisor* |
| Telephone | *0406586318* |
| Email | *luke.baitch@optusnet.com.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:

**Local HREC Office contact (Single Site -Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *Judy Rumler* |
| Position | *Administrator officer* |
| Telephone | *0260584586* |
| Email | *judy.rumler@awh.org.au* |

**Consent Form – Parent/Guardian**



**Declaration by Parent/Guardian**

I have read the Participant 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 the 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.

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| --- | --- | --- | --- |
|  |  |  |  |
|  | Name of Child (please print) |  |  |
|  |  |  |  |
|  |  |  |  |  |  |
|  | Name of Parent/Guardian (please print) |  |  |
|  |  |  |  |
|  | Signature of Parent/Guardian |  | Date |  |  |
|  |

|  |
| --- |
|  |
|  | Name of Witness\* to Parent/Guardian’s Signature (please print) |  |  |
|  |  |  |  |  |
|  | Signature |  |  Date |  |  |
|  |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior 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 |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

**Form for Withdrawal of Participation – Parent/Guardian**



**Declaration by Parent/Guardian**

I wish to withdraw the child from participation in the above research project and understand that such withdrawal will not affect their routine treatment, relationships with those treating them or the relationship with *[Institution]*.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | Name of Child (please print) |  |  |
|  |  |  |  |
|  | Name of Parent/Guardian (please print) |  |  |
|  |  |  |  |
|  | Signature of Parent/Guardian |  | Date |  |  |
|  |

Reason:

|  |
| --- |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the parent/guardian has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

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