**Tonsil and Adenoid Analysis Study (TAAS)**

**Parent/Legal Gaurdian Information Sheet**

**Principal Investigator**: Name: **Dr. James Johnston**

Position: **PhD Candidate and Research Fellow**

Address: **Department of Surgery**

**University of Auckland**

**Private Bag 92019**

**Auckland Mail Centre 1142**

Phone No: **021 171 6814**

Email: **jamesjordanjohnston@gmail.com**

Your child is invited to take part in a study analysing their tonsils and adenoids that will be removed as part of the surgery they will soon receive. Whether or not your child takes part is your (and your child’s) choice. If they don’t want to take part, they don’t have to give a reason, and it won’t affect the care they receive. If they do want to take part now, but change their mind later, they can pull out of the study at any time. As your child is not of legal age to consent for this study we ask that you read through this information sheet and make a decision on their behalf.

This Information Sheet will help you decide if you would like them to take part. It sets out why we are doing the study, what their participation would involve, what the benefits and risks to them might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you would like them to participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to allow your child to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Information Sheet and the Consent Form to keep.

This document is six pages long, including the Consent Form. Please make sure you have read and understood all the pages.

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

Your child has been invited to participate in this study because they are having an operation to remove their adenoids and tonsils. They are having these removed because they are causing problems with daily life.

The purpose of this study is to have a really close look at your child’s adenoids and tonsils in the lab after they have been removed during surgery. The tonsils and adenoids that are taken out during the operation are usually disposed of. We want to put this tissue to better use by trying to figure out what might be causing your child to have problems with them in the first place. If we can get a better understanding of what is happening in the tonsils and adenoids it may prevent some people in the future from needing the operation that your child will soon have.

This study has been approved by the Southern Health and Disability Ethics Committee.

The Principal Investigator for the study is Dr. James Johnston, PhD Candidate and Research Fellow in the Department of Surgery at the University of Auckland. James is undertaking this study as part of his PhD research under the supervision of Associate Professor Richard Douglas. If you have any questions about the study, please feel free to contact James – his contact details are listed on the front page of this document.

**What will my child’s participation in the study involve?**

Your child will not have to do anything extra by participating in this study, except to give permission for us to use the tissue that will be removed during the surgery, and allow us to take a maximum of 6 swabs of the area over their tonsils and adenoids (while they are under general anaesthetic). We may also take a blood sample to match what we see in the blood with what we find in the tonsil tissue. We will also review relevant medical records in your child’s file relating to their operation.

Participation in this study will not affect the care that your child receives in any way. All we will be doing is using the tissue that is normally discarded for scientific purposes.

**What will happen to my child’s tissue samples?**

Your child’s tissue, swab and blood samples will be sent to the University of Auckland laboratory where the samples will be stored in a secure freezer for up to five years for analysis. This is to give the researchers sufficient time to conduct the necessary studies. Your child’s samples will be assigned a code number rather than any identifiable information such as their name or NHI number. The study investigators will ensure that the link between your child’s name and this code number is kept confidential and will never be released.

Any samples remaining after this time will be destroyed by incineration. If you make a specific request it may be possible for some or all of the samples to be returned to you/your child.

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with storing your child’s tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs.  However, it is acknowledged that individuals have the right to choose.

**What are the possible benefits and risks of this study?**

There are no foreseeable risks, side effects, or discomfort related to participating in this study. The blood sample will be taken when an intravenous line is placed during surgery so that no additional needles are required.

Your child will not benefit directly from participating in this study. However we hope to increase our knowledge about tonsil and adenoid tissue which could lead to advances in treatment, meaning less people will need this operation in the future.

**What if something goes wrong?**

If your child were injured in this study, which is unlikely, they would be eligible for compensation from ACC just as they would be if they were injured in an accident at school or at home. This does not mean that their claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If their claim is accepted, your child will receive funding to assist in their recovery.

If your child has private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect their cover.

**What are the rights of participants in this study?**

Your child’s participation in this study is entirely voluntary (by choice). Your child does not have to take part in this study, and if you choose not to take part, your child will receive the usual care.

Participation in this study will be stopped should any harmful effects appear or if the doctor feels it is not in your child’s best interests to continue.

If you do agree to take part, your child is free to withdraw from the study at any time, without having to give a reason and this will in no way affect your child’s future health care.

Participants have the right to access information about them collected as part of the study.

No material which could personally identify your child will be used in any reports on this study.

Your child’s GP can be informed about his/her participation in the study if you would like this.

We are happy to send you a lay summary of the results of this study upon its completion. It is expected results will be published as a journal article and presented at various international conferences. Please note that a significant delay may occur between data collection and publication of the results.

**What happens after the study or if I change my mind?**

Your child will have standard follow up with their doctor and receive care following the surgery irrespective of participating in the study.

All data will be stored digitally on hardware at the University of Auckland.

The data from the study will be kept for 10 years. Dr. James Johnston, University of Auckland will be responsible for the safe keeping of the data. After this time all data will be destroyed using confidential data destruction procedures.

Members of the research team (present and future) will have access to the raw data and/or your child’s clinical records during the study. Future studies may wish to include this data. Where such use goes beyond that outlined in the present application, further ethical approval will be sought.

**Who do I contact for more information or if I have concerns?**

If you have any questions, concerns or complaints about the study at any stage, you can contact:

 Dr James Johnston, Principal Investigator

 Phone: 021 171 6814

 Email: jamesjordanjohnston@gmail.com

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Māori Health Team) at Auckland City Hospital and Starship Childrens Hospital by telephoning 09 486 8324 ext 2324.

If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by telephoning 09 486 8920 ext 3204.

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz

**Tonsil and Adenoid Analysis Study (TAAS)**

**Consent Form for Parent/Legal Gaurdian**

**on Behalf of Study Participant**

**If you need an INTERPRETER, please tell us.**

**Please tick to indicate you consent to the following:**

|  |  |  |
| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Study Information Sheet.  | Yes 🞏 | No 🞏 |
| I have been given sufficient time to consider whether or not to consent to participation in this study. | Yes 🞏 | No 🞏 |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | Yes 🞏 | No 🞏 |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this assent form and information sheet. | Yes 🞏 | No 🞏 |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw my child from the study at any time without this affecting their medical care. | Yes 🞏 | No 🞏 |
| I consent to the research staff collecting and processing information, including information about my child’s health. | Yes 🞏 | No 🞏 |
| If I decide to withdraw my child from the study, I agree that the information collected about my child up to the point when I withdraw may continue to be processed. | Yes 🞏 | No 🞏 |
| I consent to my child’s GP or current provider being informed about participation in the study and of any significant abnormal results obtained during the study. | Yes 🞏 | No 🞏 |
| I consent to the researchers storing tonsil and adenoid samples and a blood sample for up to 5 years for later use as a part of this study. | Yes 🞏 | No 🞏 |
| I agree that the tonsil and adenoid samples and blood sample will be disposed of using established guidelines for discarding biohazard waste. | Yes 🞏 | No 🞏 |
| I request the tissue samples be returned to me (where it is safe to do so). | Yes 🞏 | No 🞏 |
| I understand that my child’s participation in this study is confidential and that no material, which could identify them personally, will be used in any reports on this study. | Yes 🞏 | No 🞏 |
| I understand the compensation provisions in case of injury during the study. | Yes 🞏 | No 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 | No 🞏 |
| I understand my responsibilities as parent/legal gaurdian of a study participant. | Yes 🞏 | No 🞏 |

**Declaration by parent/legal gaurdian of participant:**

I hereby consent on behalf of ………………………………………………………… to take part in this study.

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| --- |
| Parent/Legal Gaurdians name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant’s parent/legal gaurdian, and have answered questions about it.

I believe that the participant’s parent/legal gaurdian understands the study and has given informed consent for their child to participate.

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| --- |
| Researcher’s name: |
| Signature: | Date: |