**INFORMATION SHEET FOR CHILDREN (5-11 years)**

We would like to ask you to take part in our study called the **Airway Intervention Registry (AIR)**.



**What is our project about?**

We want to collect information about children from all over the country who are having the same operation as you.

We will look at the information to try and help how we care for children, like you, in the future.

**Why have I been asked to take part?**

You have been asked to take part because of the airway problem you have.

**Has anyone else checked the study is OK to do?**

Yes. A group of people called the Research Ethics Committee have checked the project.

**Do I have to take part?**

No. It is up to you and your family. If you want to take part and then change your mind, that’s OK too. The researcher won’t be cross! If you want some more time to think about it, that’s OK. You can decide to take part later.

**![C:\Users\jonesr18\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\8PRB0T86\MC900390944[1].wmf]()What happens?**

All we do is collect information from you. Your nurse or doctor will give us information about your health and treatments, and your family members will be asked some questions about how you have been feeling lately.

**Is our research project safe?**

We will only be collecting information about you and your operation. It will not change the treatment that your doctor has planned for you. If you are unhappy about something, tell us or tell your family. The researcher will listen and help. Your family has more information on this.

**Will anyone else know that I am taking part?**

No-one else will know, unless they are part of this project.

**What if I still have questions?**

Please ask! You can ask your family to ask us for you.

Thank you

**INFORMATION SHEET FOR YOUNG PEOPLE (12-15 years)**

We would like to ask you to take part in our research study called the **Airway Intervention Registry (AIR)**.

Please read this information carefully and talk to your mum, dad or carer about the study. If there is anything that is not clear, or you would like to know more, please ask us. Take time to decide if you would like to take part. It is up to you if you want to do this. If you don’t then that’s fine, you’ll be looked after at the hospital just the same.

WHY ARE WE DOING THIS RESEARCH?

We want to collect information on the health and treatment of people who have a specific airway problem called Respiratory Papillomatosis (where wart-like growths develop in the airway). We are doing this to make sure that the care of people with this problem improves.

WHY HAVE I BEEN ASKED TO TAKE PART?

You have been asked to take part because you have Respiratory Papillomatosis, and we want to find a way of helping to treat you and others who have the same airway problems. We would like to get extra information about the treatments available for this problem. There are only a small number of people who are diagnosed with this problem each year, and an even smaller number are being treated regularly in hospital. We are setting up an online system to collect information from patients across the UK and we would like your permission to include your data.

DO I HAVE TO TAKE PART?

No. It is entirely up to you. If you do decide to take part, you will be asked to sign a form to say that you agree to take part (an **assent form**) and your parents will be asked to sign a form to say that they agree for you to take part (a **consent form**).

You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive whilst in hospital. If you would like more time to decide, that’s fine. You can tell us later if you want to take part.

WHAT WILL HAPPEN IF I TAKE PART?

The medical staff at your hospital will enter your health information into the online system and keep it up-to-date. Some of the information we would like to know is about how your airway problem affects your daily life and how this new treatment changes your quality of life over time.

To get this information, your mum, dad or carer will be invited to complete relevant survey forms during your meeting with the medical staff. Completion of these survey forms is optional and your health information can be entered into the online system by medical staff without your parent or guardian taking part in the surveys.

By taking part in this research study, we will make sure that all your information is treated as private and that it will not be shared with anyone else. Nobody will use this information to contact you.

WHAT WILL I BE ASKED TO DO?

You will not be asked to do anything extra as a result of the research study. By taking part all we do is collect information from you. Your nurse or doctor will give us information about your health and treatments, and your family members will be asked some questions about how you have been feeling lately.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

We will collect all the information together and decide if it is useful in telling us if we can manage Respiratory Papillomatosis better in the future.

If the online Registry closes, your data will be returned to your local hospital team (if they want it), otherwise it will be deleted or destroyed.

CONTACT FOR FURTHER INFORMATION

If you have any questions about the use of your data, or if you change your mind and want your information removed, please contact your local hospital team (their details are provided below).

If you would like any further information, you should contact:

*[Place holder for Dr name at hospital/institution where research is being conducted:*

*NAME:*

*POSITION:*

*WARD:*

*TEL:]*

Thank you for reading this leaflet

**INFORMATION SHEET FOR PATIENTS (16 years and over)**

We would like to ask you to take part in the online database named the **Airway Intervention Registry (AIR)**.

Before you decide we would like you to understand why the research is being done and what it would involve for you. **One of our team will go through the information sheet with you and answer any questions you have.**

WHAT IS THE PROJECT ABOUT?

Online databases, also called registries, containing clinical information about people with different health problems are used around the world to help with medical research and improve patient care. Our project focuses on patients with the specific airway problem of Respiratory Papillomatosis (in which wart-like growths develop in the airway).

To ensure that the care of people with Respiratory Papillomatosis improves, we would like to collect information on the health and treatment of as many people who have these conditions as possible.

We are particularly interested in capturing additional information about the treatments for Respiratory Papillomatosis which are currently being used in the NHS. As only a small number of people are diagnosed with this problem each year, and an even smaller number are treated regularly in hospital, we are setting up an online database, to collect information from patients across the UK and are requesting your permission to include your data.

DO I HAVE TO TAKE PART?

It is up to you to decide if you want your data entered into the Registry. If you agree to your data being included in the registry, we will then ask you to give written permission and sign a document called a “consent form”. If you change your mind at any time, and no longer want your data entered into the Registry, you can ask for your data to be removed, and you will not have to give a reason why. The quality of care you receive will not be affected by your decision to take part, or not take part in the Registry. If you would like more time to decide, that’s fine. You can tell us later if you want to take part.

Some of the information we would like to know relates to how your airway problem affects your daily life and how the treatments you receive change your quality of life over time. In order to obtain this information, your parent or guardian will be invited to complete relevant survey forms during your consultation with the medical staff. Completion of these survey forms is optional and your clinical data can be entered into the Registry by medical staff without your parent or guardian taking part in the surveys.

WHAT WILL HAPPEN IF I TAKE PART?

The medical staff at your hospital will enter your clinical data onto the online Registry and keep it up-to-date. This information will be used to track your health over time and in order to do so we require your date of birth and NHS number to make sure that all information collected is indeed your information. These two pieces of information are described as ‘identifiable information’. This is because the combination of these pieces of information can be used to personally identify you, however please note that nobody will try and use this information to find out who you are, and nobody will use this information to contact you.

Your date of birth and NHS number will only be available to the medical staff treating you at your hospital, and to the organisation who built the online Registry. The organisation who has built the online Registry will use your date of birth and NHS number to monitor your hospital visits over time, and will also use this information to link to other online databases to check that data held on you is accurate and to obtain additional information (for example how many times you have visited the Accident and Emergency Department).

In taking part in this Registry we will make sure that all your data is treated as private, and that your date of birth and NHS number will not be shared with anyone else. When we write a report based on the results of the Registry we will remove all identifiable information, and nobody will be able to identify you.

HOW WILL MY DATA BE USED?

Data from the Registry will have many uses. A few examples of these are:

* to determine the short-term and long-term safety and effectiveness of the various treatments used in Respiratory Papillomatosis
* to determine if any patients achieve better or worse outcomes following the different treatments
* to identify any other patient characteristics (e.g. age, gender, medications) which may influence how successful a particular treatment is
* to update guidance, which is distributed across the UK, and provide information for planning future treatments for people with Respiratory Papillomatosis.

If anyone else wants to use information from the Registry they will have to make a formal application and get approval from two separate committees. If both committees give their approval, then we will share information with them, however we will never give out your date of birth or NHS number.

If the online Registry closes, your data will be returned to your local hospital team (if they want it), otherwise it will be deleted or destroyed.

In accordance with UK Data Protection Bill 2018, those responsible for your data, once it is entered onto the Registry, are your local hospital and the organisation who built the Registry (The Newcastle upon Tyne Hospitals NHS Foundation Trust). If you have any questions about the use of your data, or if you change your mind and want your information removed, please contact your local hospital team (their details are provided below).

If you require any further information, please do not hesitate to contact the doctor below:

*[Place holder for Dr name at hospital/institution where research is being conducted:*

*NAME:*

*POSITION:*

*WARD:*

*TEL:]*

Thank you for reading this leaflet

**INFORMATION SHEET FOR PARENTS AND GUARDIANS**

We would like to invite your child to take part in the online database named the **Airway Intervention Registry (AIR)**.

Before you decide we would like you to understand why the research is being done and what it would involve. **One of our team will go through the information sheet with you and answer any questions you have.**

WHAT IS THE PROJECT ABOUT?

Online databases, or registries, containing clinical information about people with different health problems are used in many countries throughout the world to help with medical research and improve the care and treatment of patients. To ensure that the care of people with Respiratory Papillomatosis continues to improve, it is essential we have detailed information on the state of health and treatment of as many people with the condition as possible.

Due to the low number of people diagnosed with Respiratory Papillomatosis, we are setting up an online UK registry to capture information on the available treatments currently being used to treat Respiratory Papillomatosis, and are asking your permission to include your child’s data.

DOES MY CHILD HAVE TO TAKE PART?

It is up to you to decide if you want your child’s data to be entered into the Registry. If you agree to the inclusion of your child’s data being included in the Registry, we will then ask you to sign a consent form. You are free to withdraw your consent at any time, without giving a reason. This would not affect the standard of care your child receives. If you prefer, you can have some more time to decide, and tell us later.

Some of the information we would like to know relates to how your child’s airway problem affects your daily life and how various treatments change your quality of life over time. In order to obtain this information, you will be invited to complete relevant survey forms during your consultation with the medical staff. Completion of these survey forms is optional and your child’s clinical data can be entered into the Registry by medical staff without you taking part in the parent or guardian surveys.

WHAT WILL HAPPEN IF MY CHILD TAKES PART?

Your own hospital team will enter your child’s clinical data to the Registry and keep it up-to-date and may use it to follow your child’s progress. We will require your child’s date of birth and NHS number when entering your child’s data into the registry – this type of data is classed as ‘identifiable information’. Please note that this information will only be accessible to those involved directly in your child’s care, and the registry developer. This identifiable information is required in order to determine the long-term outcomes of your child’s care, and will also be used to conduct data linkage to other national databases in order to verify the information collected and obtain additional information. Note that at all times your child’s data will be treated as confidential. Your child’s identifiable information will not be used for any other purpose, and will not be shared with other organisations. For the purposes of this study all ‘identifiable information’ (i.e. date of birth and NHS number) will be removed prior to sharing results from the registry and only anonymised results of the entire study group will be published.

HOW WILL MY CHILD’S DATA BE USED?

Data from the Registry will have many uses. A few examples of these are:

* to determine the short-term and long-term safety and efficacy of various interventional procedures used in the treatment of Respiratory Papillomatosis, conducted across a large UK population
* to determine if any patient subgroups achieve better or worse outcomes following the different treatments
* to identify any other demographic or clinical factors which may influence the outcome of the different treatments
* to update national guidance and provide information for planning future services for people with Respiratory Papillomatosis.

The use of any information from the Registry by other organisations will require the approval of a Steering Committee. This will be made up of Ear Nose and Throat specialists from across the UK, who are involved in the clinical pathway of patients diagnosed with Respiratory Papillomatosis, representatives from professional societies and the National Institute for Health and Care Excellence (NICE). A data protection and information governance ethics expert will be consulted to safeguard the use of your child’s data. Note that any application to use your child’s data will have been previously approved by an independent Research Ethics Committee, and if approved; only fully anonymised data will be shared with them.

If the Registry closes, your child’s data will be returned to their local clinic team if requested by them, otherwise it will be destroyed.

In accordance with UK Data Protection Bill 2018, the Data Controller is your child’s local hospital along with The Newcastle upon Tyne Hospitals NHS Foundation Trust (who developed and host the online registry). If you have any questions about the use of your child’s data, or if you want your child’s information removed from the Registry, please contact your child’s local clinic team.

If you require any further information, please do not hesitate to contact the doctor below:

*[Place holder for Dr name at hospital/institution where research is being conducted:*

*NAME:*

*POSITION:*

*WARD:*

*TEL:]*

Thank you for taking the time to read this leaflet

**ASSENT FORM FOR CHILDREN**

**To be completed by the child (under 16 years) and their parent/guardian**

TITLE OF PROJECT:

Airway Intervention Registry (AIR)

Child (or if unable, parent on their behalf)/young person to circle all they agree with:

|  |  |  |
| --- | --- | --- |
| Do you understand what this project is about? | Yes | No |
| Have you asked all the questions you want? | Yes | No |
| Have you had your questions answered in a way you understand? | Yes | No |
| Are you happy to take part? | Yes | No |

**If any answers are ‘No’ or you don’t want to take part, don’t write your name!**

If you do want to take part, you can write your name below:

Your name:

Date:

The researcher who explained this project to you needs to sign too:

Print name: **…………………………………………………………………………………….**

Signature: **………………………………………………………………………………………**

Date: **……………………………………………**

Thank you for your help

**Patient Consent Form**

**To be completed by patients aged 16 years or over**

TITLE OF PROJECT:

Airway Intervention Registry (AIR)

NAMES OF INVESTIGATORS:

*[Place holder for Dr name at hospital/institution where research is being conducted:*

*NAME:*

*POSITION:*

*WARD:*

*TEL:]*

Place initials

in each box

CONSENT:

1. I confirm that I have read and understood the information sheet dated

February 2018 (Version 1.5). I have had the opportunity to consider

the information, ask questions and have had these answered

satisfactorily

1. I understand that I am taking part in this project entirely voluntarily and

that I am free to withdraw my consent at any time without giving any

reason, without my medical care or legal rights being affected

1. I understand that the information collected about me will be used to

support other research in the future, and may be shared anonymously

with other researchers.

1. I understand that patient confidentiality will be maintained at all times

**I agree to my data being added to the AIR Register**

**DETAILS:**

**Name of patient: ………………………………………………………………………………....**

**Signature : ………………………………………** **Date : …../……/……**

**Name of person taking consent: ……………………………………………………………..**

**Signature : ……………………………………… Date : …../……/……**

**PARENT/GUARDIAN CONSENT FORM**

**To be completed by the parent/guardian for children under 16 years old**

TITLE OF PROJECT:

Airway Intervention Registry (AIR)

NAMES OF INVESTIGATORS:

*[Place holder for Dr name at hospital/institution where research is being conducted:*

*NAME:*

*POSITION:*

*WARD:*

*TEL:]*

Place initials

in each box

CONSENT:

1. I confirm that I have read and understood the information sheet dated

February 2018 (Version 1.5). I have had the opportunity to consider

the information, ask questions and have had these answered

satisfactorily

1. I understand that my child is taking part in this project entirely

voluntarily and that I am free to withdraw my consent at any time without

giving any reason, without medical care or legal rights being affected

1. I understand that the information collected about my child will be used to

support other research in the future, and may be shared anonymously

with other researchers.

1. I understand that patient confidentiality will be maintained at all times
2. **I agree to information from my child being used in the AIR Register**

**DETAILS:**

**Name of patient: …………………………………………………………………………………**

**Name of parent/guardian: ……………………………………………………………………...**

**Signature : ………………………………………** **Date : …../……/……**

**Name of person taking consent: ……………………………………………………………..**

**Signature : ……………………………………… Date : …../……/……**