

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