

## **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