

**IRAS ID:**

**Study ID:**

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**Parent Information Document**

(For parents of children attending hospital for a procedure requiring general anaesthesia)

*“Sampling Nose of Toddlers and Young Children”*

You and your child are being invited to consider taking part in a research study. When your child has a general anesthetic as part of their care we would like to collect some samples to learn more about how healthy children are protected against respiratory infections. Before you decide if you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information.

**What is the study about?**

We all have bacteria in our nose even when we are healthy. About half of the children under six years age in the UK carry a bacteria (called pneumococcus) at any time. Usually their immune system prevents this bacteria from going to the lungs. However, sometimes the immune system is not able to prevent the bacteria from entering the lung and this can lead to chest infections. Current vaccines protect against some but not all of types of pneumococcus bacteria.

We hope that by studying how healthy children’s immunity controls the bacteria in the nose, we can use this information in future to develop vaccines that protect against all types of pneumococcus bacteria.

**Why has my child been chosen?**

Your child has been chosen because they are generally well and attending hospital for an operation or other procedure that requires them to be asleep under a general anaesthetic.

**What will happen if I agree for my child to take part?**

* You will be asked to answer a few questions about your child and about any medicines they might be taking.
* When your child is asleep, the nurse or doctor we will gently brush the inside of the nose a cotton swabs (like cotton buds) to see if your child is carrying the pneumococcus bacteria. We will also brush the back of the throat with another cotton swab to see if your child has any viruses. We then place a filter strip (like small blotting paper) in the nose for 1-2 minutes to collect some nasal liquid. We will also make two small scratches on either side of the nose with a very small probe (similar to a toothpick) to collect a small number of cells from the nose. They will not feel any of this happen. These tests will allow us to look at the way healthy children respond to bacteria or viruses commonly found in the nose.
* While your child is asleep, we will also take a small amount of blood from a vein. In most cases this will be taken from a line in the vein required during the anaesthetic. We will take no more than 3mL of blood (half a teaspoon).
* Samples collected may be used immediately or stored without any personal details in the Liverpool School of Tropical Medicine or other research institutes who are supporting relevant respiratory research.

**Are there any disadvantages to my child taking part in this study?**

We are collecting small samples that have been collected in many children before. We do not expect any discomfort as your child will be asleep. Sometimes there can be a very small amount of blood when scratching the nose. When taking blood from a vein this can cause a small bruise but whenever possible we will collect the blood from the line in the vein that is required for the anaesthesia.

**Are there any benefits to my child taking part in this study?**

No. While this study will not benefit your child directly, it may help us to understand more about how healthy children are protected from chest infections to help us to prevent pneumonia in children in the future.

**Will my child’s GP be informed of their participation in this study?**

Your child’s GP will not be informed of these samples unless you wish otherwise, in which case this can be added to their discharge letter.

**Do I have to take part?**

No. It is up to you and your child (where possible) to decide whether or not to take part. You can withdraw from the research at any time and without giving a reason. Your decisions about this will not affect the standard of care your child receives.

If you would like to take part, you will be given this information sheet to keep and be asked to sign a consent form.

**Will the information on my child be kept confidential?**

Yes, all personal information will be kept confidential and secure on password protected NHS computers. Only people involved in the study will have access to the information. We are required by Alder Hey Children’s Hospital and the Liverpool School of Tropical Medicine to keep our research results for ten years in a password protected system. Research results cannot be traced back to you or your child. This study has been approved by the Liverpool Children’s Research Ethics Committee, which includes lay members representing the local community.

**What will happen to the results of the research study?**

The results will be published in medical journals and will contribute to the information needed when we plan future studies to develop new vaccines against chest infections. We will also put a summary of the results in time onto the web site of the Liverpool School of Tropical Medicine.

**What if you have any problems or would like further information about the study?**

You can contact:

Lead Research Nurse \*\*\* Email: \*\*\* Phone: \*\*\*

**What if you have a concern or complaint to make about the study?**

You can contact:

The Patient Advisory Liaison Service (PALS)

Alder Hey Children’s Hospital

E Prescot Rd, Liverpool L14 5AB

Telephone: 0151 252 5374

Email: pals@alderhey.nhs.uk