

## **PARENT/LEGAL GUARDIAN INFORMATION SHEET**

### **Study title**

**Paediatric Oximetry Algorithms** ~~Prospective study of oximetry in children following adenotonsillectomy for severe obstructive sleep apnoea (OSA).~~

Sheffield Children's NHS  
NHS Foundation Trust



### **Invitation paragraph**

You and your child are being invited to take part in a research study. Research is important in helping us to improve ways of treating medical conditions. Before you decide whether 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. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you and your child if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you want your child to take part.

### **Part 1 – to give you first thoughts about the project**

#### **1. What is the purpose of the study?**

We use pulse oximetry as a way of measuring and monitoring children's blood oxygen levels in many situations, to diagnose respiratory conditions or to monitor treatment. The monitors that we use are accurate and safe and have been used for many years. The way they are set up to analyse the blood oxygen levels uses a calculation called an algorithm. There are algorithms for newborn babies and adults but no algorithms for children. We think that designing an algorithm for children will improve the accuracy of the information we get from the oxygen saturation monitors.

The purpose of this study is to collect data from children already having their oxygen levels monitored for a clinical reason, so that we can work out an algorithm for children. Children that have an operation to remove their tonsils and adenoids because of obstructive sleep apnoea sometimes go to the High Dependency Unit after their operation. These are usually children that had an abnormal sleep study before the operation, or children with other medical conditions. We have found though that very few of these children have any problems with their breathing after the operation and that going to the High Dependency Unit probably isn't necessary for most children. We are carrying out this research study to check for any oxygen or breathing problems after the operation, to help us to decide which children really need to be observed on the High Dependency Unit and which children are safe to go to a ward after their operation.

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This research will be conducted by Dr Ruth Kingshott, an expert in oximetry and research and Heather Elphick, a respiratory consultant and Emily Watson-Thoday, who is a medical student.

## **2. Why has my child been chosen?**

We want to collect blood oxygen information from children that are already having an oximetry test, as requested by their nurse or doctor. Your child is having this test done and this is why he/she has been chosen. ~~look for breathing problems in children who are having operations to have their tonsils and adenoids removed.~~

## **3. Does my child have to take part?**

No. It is up to you and your child (wherever possible) to decide whether or not to take part. You are both free to withdraw from the research at any time and without giving a reason.

If you are happy to take part, and are satisfied with the explanations from the research team, you will be asked to sign a consent form. If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign an assent form with you, if they want to. You will be given a copy of the information sheet and the signed consent/assent forms to keep for your records.

## **4. What will happen to my child if we agree to take part?**

Your child has already been asked to have their blood oxygen levels monitored by their nurse or doctor. For this test, they will have an oxygen saturation monitor attached to their toe with a plaster. If you take part in the research study, we will attach a second oximeter with a second plaster to another toe, ideally on the same foot, but possibly on the other foot. ~~an oxygen saturation monitor to your child's toe with a plaster. The two monitors will be connected to a box called a data-logger, which will collect the oxygen information that we need for the research. This will not affect the information that is collected for the test that your doctor or nurse has asked for as this will be analysed separately. He/she will have had this test done already at home a few weeks before the operation.~~ The oximeters will stay on for as long as your doctor or nurse has requested, and then they will both be removed. ~~until your child is ready to go home. The medical student will also be writing down any problems and may ask you some questions.~~

Here is a photo of the equipment that we will use. The oximeter is about the size of a small shoebox and the only part that will come into contact with your child is the plaster on his/her toe.



One of the research team will also write down details on a form such as where the plasters have been placed and your child's age, but there will be no information on the form that will identify your child.

#### **5. What will we have to do?**

You will not be asked to do anything other than to reassure and comfort your child. You will may be asked to write down any breathing problems or disturbances your child has if he/she has the monitorst~~o stay~~ overnight, but this is needed by the clinical staff and is not part of the research.

#### **6. What are the possible disadvantages and risks of taking part?**

If at any time you or your child feels distressed by the second plasterthat the actual or perceived distress is too great, please don't hesitate to tell the research doctor/nurse and we will stop the recordings.

#### **7. What are the possible benefits of taking part?**

Your child will not benefit from being part of this study. However the information we collect may help us to treat future patients better.

#### **8. What happens when the research study stops?**

We will collect all the oxygen readings from both monitors and give them to a company called Viamed who will write the new algorithm. All of the information that is given to Viamed will be anonymized and your child will not be identifiable. -information together and we will decide whether we can use it to decide which children need to be nursed on the High Dependency Unit after the adenotonsillectomy operation.

#### **9. What if there is a problem?**

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Any complaint about the way you or your child have been dealt with during the study or any possible harm you or your child might suffer will be addressed. The detailed information on this is given in Part 2.

**10. Will my child's taking part in the research project be kept confidential?**

Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence. The details are included in Part 2.

**11. Contact for further information**

If you would like any further information about this study you could contact:

Name: Heather Elphick

Designation: Consultant Paediatrician

Hospital/Department: Sheffield Children's Hospital

Tel: 0114 2717400

**This completes Part 1 of the Information Sheet.**

**If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.**

## **Part 2 - more detail – information you need to know if you still want to take part.**

### **12. What will happen if we don't want to carry on with the research?**

If you withdraw from the study, we will destroy all your child's identifiable data if you wish, but we will need to use the data collected up to their withdrawal.

### **13. What if there is a problem?**

#### **Complaints**

If you have any cause to complain about any aspect of the way in which you or your child has been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not compromised in any way because you have taken part in a research study. If you have any complaints or concerns please contact either the project co-ordinator:

Name: Heather Elphick  
Designation: Consultant Paediatrician  
Hospital/Department: Sheffield Children's Hospital  
Tel: 0114 2717400

Otherwise you can use the normal hospital complaints procedure and contact the following person:

Mrs [Julie Mathers](#)  
~~Linda Towers~~  
Patient Advice & Liaison Co-ordinator  
Sheffield Children's NHS Foundation Trust  
Tel: 0114 271 7594

#### **Harm**

If your child is harmed by taking part in this research project, there are no special compensation arrangements. If your child is harmed due to someone else's fault, then you may have grounds for a legal action—but you may have to pay for it.

### **14. Will taking part in this study be kept confidential?**

All information which is collected about your child during the course of the research will be kept strictly confidential. Any information about your child which leaves the hospital will have their name and address removed so that your child cannot be recognised from it. Once the study is complete all information will be kept for 6-12 months and then destroyed in accordance with standard operating procedures.

Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 1998.

The measurements will be stored on a computer. The data will be coded and only authorised people involved in the research study will have access.

Your child's medical notes may also be looked at by other people within the hospital involved in the running and supervision of the study to check that it is being carried out correctly.

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

When the study has finished we will present our findings to other doctors, and we will put the results in medical magazines and websites that doctors read. They will be anonymous, which means that your child will not be able to be identified from them. You will be able to obtain the results from Dr Elphick if you wish to see them.

**16. Who is organising and funding the research?**

The research has been funded by the Small Business Research initiative (SBRI), which is a government funded initiative.  
~~is being organised by Sheffield Children's NHS Foundation Trust and Sheffield University medical school~~

**17. Who has reviewed the study?**

The study has been reviewed by reviewers and panel members of the SBRI. ~~tutors at Sheffield University.~~

**18. How can we find out more about research?**

The Clinical Research Facility at this hospital has a **Taking Part** section on its website <http://www.sheffieldchildrens.nhs.uk/research> or you could contact the hospital Clinical Research Facility:

Mrs Gillian Gatenby  
Directorate Manager of Research  
Sheffield Children's NHS Foundation Trust  
Tel: 0114 226 7904

**If you and your child decide to take part in this study, you will be given this information sheet and signed consent and assent forms to keep.**

**Thank you for taking the time to read this information sheet.**