**Oxygen in Paediatric Intensive Care (Oxy-PICU)**

**Participant Information Sheet (Parent/Guardian)**

**We invite you to provide consent for your child’s information to be used in a research study**

We know this is a very difficult time for you and your family. If possible, we hope you won’t mind spending a few minutes deciding on whether or not you would consent for your child’s information to be included in a research study, which aims to improve the care of children in intensive care.

Your child was having difficulty breathing when they were admitted to PICU and was put on a ventilator (breathing machine) and given extra oxygen. Oxygen is one of the most common treatments used in emergency situations. Doctors and nurses adjust oxygen treatment based on how much oxygen there is in the blood, known as oxygen saturations. We know that very low oxygen saturations are harmful but we think very high saturations may also be dangerous.

We are doing this study (Oxy-PICU: Oxygen in Paediatric Intensive Care) to find out whether aiming for one oxygen saturation when treating children on a ventilator in intensive care is better than another. We hope to include 2,000 children from 15 NHS PICUs.

Before you decide whether you want to give permission for your child’s information to be included in this study, it is important for you to understand why this research is being done and what it involves. You are free to decide whether or not you wish your child’s information to be included in this study – you may wish to talk to friends and family about your decision. Please ask the nurse or doctor who has spoken or written to you about Oxy-PICU if there is anything that is not clear or if you would like more information.

**Important things you need to know**

* Your child came to intensive care in an emergency; it was important to treat them as quickly as possible.
* Giving extra oxygen is standard treatment for children in intensive care across the world, but the best oxygen level to aim for is not known.
* We want to find out whether aiming for a lower oxygen saturation (88-92%) is safer than commonly used targets (above 94%).
* As this was a medical emergency, your child was given extra oxygen to maintain their oxygen saturation between either 88-92% or above 94%.
* This type of research is called ‘research without prior consent’ and is done in emergencies when comparing treatments to find out which is best.
* We are now asking for your consent for your child’s information to be included in Oxy-PICU.

**If you have any questions, please contact:**

**Principal Investigator Research Nurse**

Name: <NAME> Name: <NAME>

Telephone:<NUMBER>Telephone: <NUMBER>

**1) Why are we doing this study?**

**Breathing difficulties are the most common reason for a child to need an emergency admission to intensive care and a ventilator with extra oxygen is often a vital part of their treatment. There have been huge safety improvements in ventilator use over the last 25 years. We now use ventilators more gently, meaning the lungs are much less likely to be injured.**

**We know that adding too much oxygen can injure the lungs and possibly other parts of the body. Current advice is not to use oxygen to achieve ‘normal’ oxygen saturations (98-100%) when the lungs are sick but to aim a little lower (88-97%). Because there isn’t much evidence about what is best, doctors and nurses tend to aim for the higher numbers.**

**Recent research in adults has found that high oxygen saturations can lead to worse outcomes. We don’t know if this harm is because of the oxygen level itself or a side-effect of the more intensive treatment needed to keep oxygen levels high. Differences in how children’s bodies work compared to adults mean the results of this research cannot be applied to children.** The only research in children was carried out in very premature babies (24-27 weeks gestation) which found that lower oxygen targets are no better. However, this finding cannot be applied to all children.

Our aim is to find out whether it is better for doctors and nurses to aim for oxygen saturations at the lower end of the recommended range (88-92%), or at levels often currently used (above 94%). Both of these targets are used in standard practice at the moment, but it is not known which is better. That is why we are doing this research. We monitor the study closely and, if one treatment is better or worse, we will stop the study.

**2) What do I need to know about the treatments used in this study and the possible side effects?**

Using oxygen reduces the effort needed to breathe and increases oxygen in the blood. Oxygen is the most common drug used in emergency situations; there are no safety concerns about its use in children. As with all treatments, there may be complications, but these are rare.

The benefits and risks of maintaining lower blood oxygen levels are unclear at this time – which is why this research is needed. By answering this question, we will help to improve the future treatment of children in intensive care.

**3) How was it decided which oxygen level was aimed for in my child?**

Oxy-PICU is a randomised controlled trial – which means that each child is randomly put into one of two groups:

* children in Group 1 receive treatment aiming to maintain oxygen saturations at above 94%
* children in Group 2 receive treatment aiming to maintain oxygen saturation values of 88-92%

To make sure it is fair, children are put into groups at random by a computer programme. This means that your child had an equal chance of being in Group 1 or Group 2. If this trial wasn’t happening, your child still would have had their oxygen levels maintained somewhere between 88-100%.

Your child received all other treatments they needed. Your child’s doctors and nurses were free to stop your child participating in the trial if they felt that was best.

**4) Why am I being asked after my child has been given the treatment, rather than before?**

As this was a medical emergency, we could not delay the urgent treatment your child needed to talk about this study. We are therefore asking you about the study after the emergency. This is called “research without prior consent”, a method of consent which is used in other emergency studies.

**5) What will happen next?**

1. **If you** **agree** **for your child’s information to be included in the study**, the hospital research team will use the anonymised information already collected for Oxy-PICU. This information will be securely sent to the Intensive Care National Audit & Research Centre (ICNARC) who are coordinating the study.
2. Information collected from research studies can be used to answer many important research questions, beyond those planned in the original study. This has the potential to provide real benefit to patients, the NHS and the scientific community. We would like your permission to share anonymised information about your child with other researchers if we feel it could contribute to answering important questions. Examples of this data would be age, treatments given or how long children stay in hospital. It would not be possible to identify you or your child from this data.
3. When designing and conducting studies, we value the input of parents and carers who have experienced PICU. If you would like to take part in this – for example, in an interview discussing a new research study – we will keep your contact details for up to five years after the end of the study.

You do not have to agree to take part. It is up to you to decide whether your child’s information will be included in the study.

**6) How will we use information about your child?**

We will need to use information from your child’s medical records for this research project.

This information will include your child’s initials, NHS number, name and your contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you or your child are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you and your child safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

**7) What are my choices about how my child’s information is used?**

You can stop being part of the study at any time without giving a reason. We will keep information about your child that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about your child.

**8) Where can I find out more about how my child’s information is used?**

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
* by asking one of the research team
* by sending an email to oxypicu@icnarc.org

**9) What will happen to the results of this study?**

The results of the study will appear in scientific journals. You will be able to find the results on ICNARC’s website ([www.icnarc.org](http://www.icnarc.org)) within a year after the study is completed. It will not be possible to identify any person who has taken part in the study in any journals, reports or articles.

ICNARC will keep identifiable information about you and your child for no longer than one year after the study has finished (unless you have agreed otherwise) and the rest of the research data will be kept for up to 15 years. [Local NHS Trust] will keep identifiable information about your child from this study for fifteen years after the study has finished. All information will be stored securely. ICNARC will not receive new identifiable information about you or your child that has emerged from this study.

**10) Who is funding and organising the study?**

The study is funded by the National Institute for Health Research, Health Technology Assessment Programme. Professor Mark Peters is leading the study (Chief Investigator). The Intensive Care National Audit and Research Centre (ICNARC) are sponsoring and managing the study.

The research team are qualified to do this study because they have all the specialties and skills needed, including caring for unwell children and doing health research. Parents of children who have experienced intensive care have been involved in developing of the study, including this information sheet and how you were asked to take part.

**11) What if there is a problem?**

**Complaints:** If you have a concern about any aspect of the Oxy-PICU Study, you should ask to speak with the Principal Investigator <Insert NAME> or research team (contact details are on the first page) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or the Patient Advisory Liaison Service (PALS), contactable on <Insert PALS number>. You may also have the right to lodge a complaint with the Information Commissioner’s Office (ICO) ([www.ico.org.uk](http://www.ico.org.uk)).

**Harm:** It is very unlikely that the research would cause any harm, but we are obliged to mention this possibility. If something does go wrong, and the participant was harmed during the study and this is due to the design of the study or someone’s negligence then you may have grounds for a legal action for compensation against <TRUST> but you may have to pay your legal costs. The normal NHS complaints mechanisms will be available to you.

**12) Who has reviewed the study?**

All NHS research is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. Oxy-PICU was reviewed by East of England – Cambridge South Research Ethics Committee who approved the study (19/EE/0362) and agreed it is being conducted in a correct and appropriate manner.

**We are very grateful that you are considering taking part in this study – thank you very much for your time.**