

Research in Paediatric Critical Care

Information for patients



Thank you for taking the time to read this short leaflet.

We are very sorry that your child's condition has meant they need to be looked after in our Paediatric Intensive Care Unit (PICU). We realise that this may be one of the most distressing and difficult times your family has ever experienced.

Our aim is to give the best possible care to your child, to you and to your family. For this reason we are passionate about clinical research. We believe we should offer every child in intensive care the opportunity to be involved in research.

This short leaflet explains what clinical research is – allowing you to make informed decisions for your child and your family.

What is research?

Research is a structured process leading to new information about a treatment, test or condition. This new information can be used in many different ways. Some examples of positive outcomes from research include:

1. A new drug or therapy that treats a known condition better than a previous one.
2. A new test that allows us to give you more accurate information about your child's condition.
3. A new device that would allow us to treat your child more effectively.

What types of research are there?

Research on patients is often referred to as a trial or study. Clinical research studies can broadly be split into observational and interventional.

- Observational studies are research studies performed by making observations with patients while they are receiving treatments we already use.
- Interventional studies test a new way of treating a condition. This may be a drug, a piece of equipment or something else about the way a patient is looked after. This is then compared with the usual method of treating the condition.

Why do we do research involving children?

Children and adults suffer from different diseases and conditions. The only way to understand a childhood condition is to research that condition in children.

Medical research in children leads to innovations in healthcare that can improve their health and quality of life.

The way children process and respond to medication may vary compared to adults, and according to the age of the child. Research is necessary to find the most effective dose of many medicines given to children.

Is it safe?

Every piece of research that is conducted with patients within the NHS must have approval from an ethics committee. Their role is to protect the rights and wellbeing of patients.

Research will not gain approval for conduct within the NHS unless the patient's interests prevail over those of science and society, and the research must have the potential to improve human health and wellbeing .

During interventional studies the data on patients are very closely monitored. This is done by a group of people independent from the trial and concerned solely with the purpose of ensuring safety.

Who else is involved in research?

There is a large team of nurses, doctors and administrative staff involved with research in Oxford University Hospitals. These people are experts in how to perform studies, and how to link up with other hospitals, as higher numbers of patients improve the accuracy of research. Some of these studies may involve hospitals worldwide.

Will your child benefit from research?

Your child may not benefit directly from the clinical study, but other children in the future may be helped by the information gained through your participation in the study, whatever the findings are.

If your child takes part in an 'interventional' study, they will receive either the usual treatment, or the new treatment which is thought to have further benefit. When interventional studies are being performed, both the clinical team and the research team will usually not know which treatment your child is receiving. This is important to prevent any bias in the results.

Although your child may not benefit directly, there is good evidence that shows hospitals and departments actively involved in clinical research have better clinical outcomes.

What if you don't want your child to be involved?

The decision to take part in research is always voluntary. Your child will receive excellent care whether you decide to participate or not. You are also free to withdraw your child from any study at any time, and you do not have to provide a reason.

Once you have agreed to participate in a research study, the team will check regularly that you are happy to remain in the study.

Finding out about research projects relevant to your child

If there is a study for which your child is eligible, you will be approached by a member of the research team together with your clinical team to have an initial discussion. They will explain the study and what it involves, and give you a chance to ask questions.

Most studies allow some time to make a decision, but some, involving treatments in very critically ill children, may require you to make a decision quickly. We are very aware that this is a stressful time for you, and will give you as long as possible to decide.

If you and (if they are old enough) your child agree to take part in a research study you will be asked to sign a consent form. If your child is too unwell to be involved in the discussions about participating in a research study you can consent on their behalf and we can discuss the study with them once they are well enough.

Results of research trials

The results of most trials are published in the form of an article in a scientific journal. As there is much work to be done collecting and analysing data, trials are often published several years after patients have been recruited. Sometimes it takes several years to recruit all the patients needed.

The research team will ensure you have access to the article once published. You will always have contact details for the study team if you want to know how the study is progressing.

Who to speak to for more information

If your child is enrolled in a research study you will be given direct lines of contact to the research team involved.

For general information about research in paediatric intensive care, anyone on the medical or nursing team will be able to help, or arrange for you to talk to the right person.

The OUH Paediatric Research Team can be contacted at any time for general information.

Telephone: **01865 231729**

Email: **soccr@paediatrics.ox.ac.uk**

If you have a specific requirement, need an interpreter, a document in Easy Read, another language, large print, Braille or audio version, please call **01865 221 473** or email **PALSJR@ouh.nhs.uk**

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