



Oxford University Hospitals
NHS Foundation Trust

Research in Paediatric Critical Care

**Information for patients
and their families**



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 Critical Care Unit (PCCU). 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 critical 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 or device that allows us to treat your child more effectively.
3. Optimising existing clinical therapies.

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.

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 only gain approval for conduct within the NHS if it has the potential to improve human health and wellbeing and on the condition that our patient's best interests are the most important priority, above answering any research questions.

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.

Research without prior consent

Often children become eligible for trials during a period of life threatening illness where decisions need to be made very quickly. As this can be the most stressful time for families it is usually not appropriate to talk in detail about research. In these cases patients will be enrolled in the studies and we will speak to you about it when things are more settled.

Research without prior consent is only used in trials that are comparing treatments already in use and where we are trying to find evidence for which is best. All research studies that use this model of consent will have been approved by an ethics committee.

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.

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.

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.

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 critical 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 Children's Research Team can be contacted at any time for general information.

Telephone: **01865 231 729**

Email: **childrensresearch@ouh.nhs.uk**

Further information

If you would like an interpreter, please speak to the department where you are being seen.

Please also tell them if you would like this information in another format, such as:

- Easy Read
- large print
- braille
- audio
- electronic
- another language.

We have tried to make the information in this leaflet meet your needs. If it does not meet your individual needs or situation, please speak to your healthcare team. They are happy to help.

Author: Paediatric Research Team
August 2024
Review: August 2027
Oxford University Hospitals NHS Foundation Trust
www.ouh.nhs.uk/information



Making a difference across our hospitals

charity@ouh.nhs.uk | 01865 743 444 | hospitalcharity.co.uk

OXFORD HOSPITALS CHARITY (REGISTERED CHARITY NUMBER 1175809)

