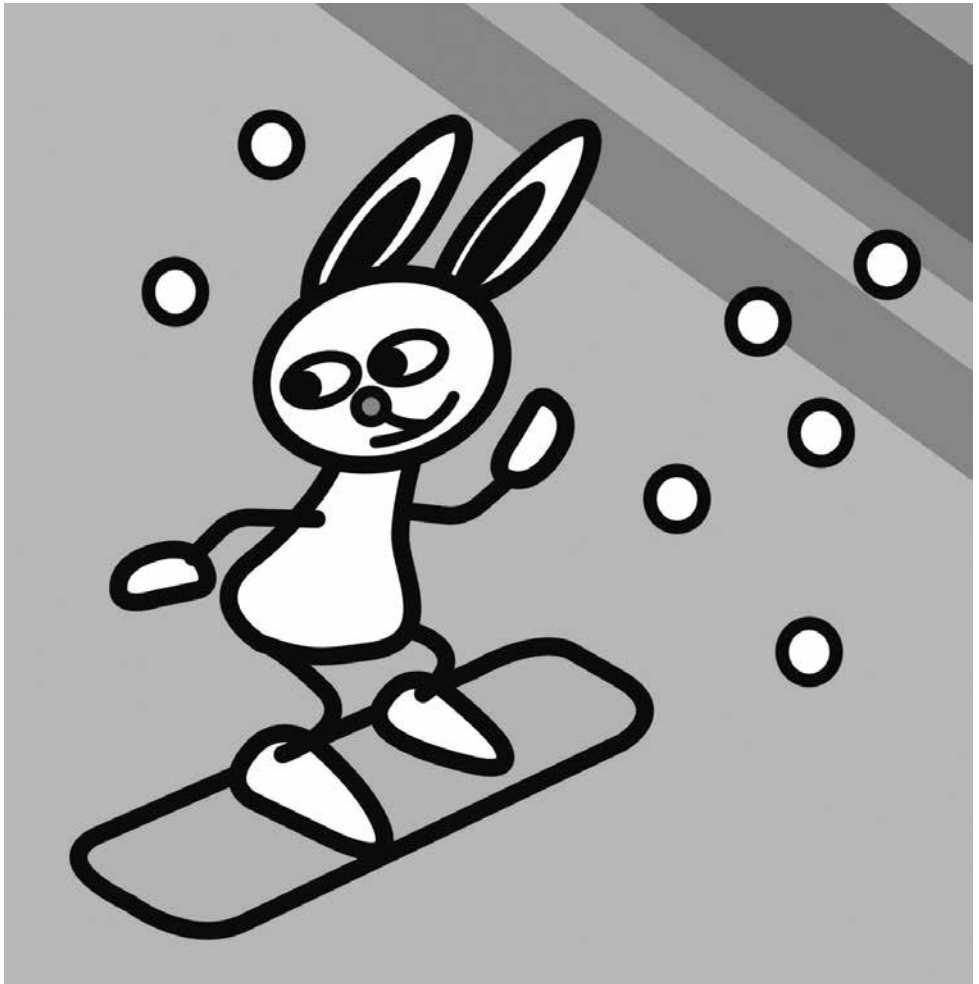


Research in the Oxford Newborn Care Unit

Information for patients/carers



Information for parents/carers



Thank you for taking the time to read this leaflet about research in the Oxford Newborn Care Unit.

Our aim is to give the best possible care to you and your baby whilst you are in the Oxford Newborn Care Unit. For this reason, we are passionate about clinical research. We believe we should offer every baby in the unit the opportunity to be involved in research.

This leaflet explains what clinical research is – allowing you to make informed decisions for your baby 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 baby's condition
- 3.** a new device that would allow us to treat your baby 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 on 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 neonates?



Babies, children and adults suffer from different diseases and conditions. The way babies process and respond to medication may vary compared to adults, and according to the age and gestational age at birth of the baby.

The only way to understand a 'neonatal' (preterm, and term up to 28 days old) condition is to research that condition in neonates. Research is necessary to find the most effective dose of many medicines given to babies.

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

How will safety be monitored?

Every piece of research that is conducted on 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 are shown to be the most important part of the study, and the research must have the potential to improve human health and wellbeing.

During interventional studies patient data is very closely monitored for any unwanted effects. This is done by a group of people independent from the trial and concerned solely with the purpose of ensuring safety.

Who will conduct the research?



As well as your baby's own doctors and nurses, there is a dedicated research team within the Oxford Newborn Care Unit and Children's Hospital.

The research team comprises doctors, nurses and administrative staff who 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 my baby benefit from research?



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

If your baby takes part in an 'interventional' study, they will receive either the usual treatment, or a 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 baby is receiving. This is important to prevent any bias in the results.

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

What if I don't want my baby to be involved?

The decision to take part in research is always **voluntary**. Your baby will receive excellent care whether you decide to participate or not. You are also free to withdraw your baby 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 baby



If there is a study for which your baby 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 and allow some time to make a decision.

We are very aware that this is a stressful time for you, and will give you as long as possible to decide.

If you agree for your baby to take part in a research study you will be asked to sign a **consent form**.

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 baby 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 the Oxford Newborn Care Unit, please talk to your clinical team or to the Neonatal Research Nurses.

Telephone: 01865 857 679

Email: sheulabarlow@paediatrics.ox.ac.uk / sharon.baugh@ouh.nhs.uk

For more information about research at Oxford University Hospitals, please visit:

www.ouh.nhs.uk/research

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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