



Oxford University Hospitals
NHS Foundation Trust

Research in the Oxford Neonatal Unit

Information for
parents and carers





Information for parents and carers

Thank you for taking time to read this leaflet about research in the Neonatal Unit.

Since the start of specialist newborn care in the 1950s, research has played a big part in helping to improve the treatment and outcomes for babies and our aim is to continue to support this work. There are multiple research studies running on the neonatal unit at any one time and there is a good chance that your baby will be eligible to take part in one or more studies.

By reading this leaflet, we hope you will understand what clinical research is and why we may approach you about research opportunities for you or your baby.



Why do we do research studies?

Research is a way of gaining knowledge and improving our understanding of diseases, treatments, and the effects of current practice. It is an important tool for improving the quality of care we provide. By choosing to take part in clinical research, you may help improve the health and future of babies who are born sick or premature. There is also evidence that shows hospitals and departments actively involved in clinical research have **better clinical outcomes**.

Who will conduct the research?

There is a dedicated research team who are part of the Oxford Neonatal Unit clinical care team. The research team comprises doctors, nurses and administrative staff who are experts in how to perform studies. Research may be performed by your baby's own doctors and nurses.

We also have a research group of doctors, nurses and scientists from the University of Oxford (the Paediatric Neuroimaging Group), embedded within the Neonatal Unit. They have a specific interest in understanding early development of the human brain.



Is it safe?

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 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.

Within the Trust, the safety and quality of all studies is also reviewed by the Research and Development Department and the Oxford University Hospitals research teams. These regulations and checks are put in place to ensure that the studies we run are designed correctly, run safely and focus on outcomes which are important to babies and their families. The safety and care of your baby and you, are always the top priority.



Finding out about research projects relevant to your baby

There are many different research projects taking place and it is important that every family is offered the opportunity to take part in research.

If your baby is eligible for a study, in most cases, you will be approached by a member of the research 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 decide.

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**.

Research without prior written consent

Often babies are eligible for studies soon after birth, or during a period of life-threatening illness, when decisions need to be made very quickly. As this can be the most stressful time for families, it is not usually appropriate to talk in detail about research.

Two types of consent are often used in these situations: deferred consent and opt-out consent. Both these consent options are only used in studies that are comparing treatments already in use and where we are trying to find evidence for which is best or where there is no study intervention but data is being collected. The research ethics committee will have approved the type of consent that can be used for each study.

Deferred Consent

In this case, your baby will be enrolled in a study if your baby meets the study criteria and we will speak to you about it when things are more settled. You will be asked for your consent for ongoing study participation and use of the information already collected.

Opt-Out Consent

In this case all eligible babies will take part unless you let a member of the neonatal team know that you **do not** want your baby to participate. You will be informed about these studies through study information included in the Parent Admission Pack. For these studies you may or may not be approached directly by the research team beforehand. Your baby does not have to take part in 'opt-out' studies. It is your choice, but you must let a member of the neonatal team know if you do not want your baby to be enrolled.



How will my baby be identified?

Different babies will be able to take part in different research studies depending on what the study is investigating. Members of the research team will review your baby's medical notes and/or your medical notes to identify whether your baby is eligible to take part in a study. If you do not want scientists within the neonatal research team to review your baby's notes, please let your baby's nurse or doctor know.

Will my baby benefit from research?

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



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.

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. You will always have contact details for the study team if you want to know how the study is progressing and you may be given the option to receive results of the study once they are available.

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 Neonatal Unit, please talk to your clinical team or to the Neonatal Research Nurses.

Telephone: 01865 857 679 or 07917 232 245

Email: neonatal.research@ouh.nhs.uk

Paediatric Neuroimaging Group, University of Oxford

Telephone: 01865 234 537

Website: neuroimaging.paediatrics.ox.ac.uk

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

Oxford University Hospitals Research

To find out more about research projects within the Oxford University Hospitals.

Website: www.ouh.nhs.uk/research

National Institute for Health Research

The nation's largest funder of health and care research, and provide the people, facilities and technology that enables research to thrive.

Website: www.nihr.ac.uk

SSNAP

A charity supporting parents on the Neonatal Unit of the John Radcliffe. You can find them near the entrance on Level 2 of the Women's Centre.

Website: www.ssnap.org.uk

BLISS

A UK charity working to support all premature and sick babies and their families.

Website: www.bliss.org.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.

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