Research in the Neonatal Unit

Information for parents and carers

Simpson Neonatal Unit
Royal Infirmary of Edinburgh

Information for parents and carers

Thank you for taking the time to read this leaflet about research in the Simpson Neonatal Unit at the Royal Infirmary of Edinburgh.

Research has played an important role in improving care for babies born prematurely or unwell. Many of the treatments and approaches used in neonatal care today are based on evidence gained through carefully conducted research studies.

Our aim is to continue improving care for babies and families through high-quality research. There are often several research studies taking place within the neonatal unit at any one time, and your baby may be eligible to take part in one or more of them.

By reading this leaflet, we hope you will better understand:

- what neonatal research involves
- why families may be approached about research studies
- how research is reviewed and monitored for safety
- what your choices are if your baby is invited to take part.

Why do we do research studies?

Research helps us improve our understanding of illness, treatments and long-term outcomes for babies requiring neonatal care.

Research studies may help us:

- improve treatments and care for premature and sick babies
- understand how babies grow and develop
- identify safer and more effective treatments
- improve support for babies and families during and after neonatal care.

By taking part in research, families may help improve care for future babies and their families.

There is also evidence that hospitals actively involved in research often achieve better clinical outcomes.

Who conducts the research?

Research within the Simpson Neonatal Unit is carried out by trained healthcare professionals including:

- doctors
- nurses
- advanced neonatal nurse practitioners
- midwives
- allied health professionals
- research staff and university researchers.

Some studies are run locally within NHS Lothian and the University of Edinburgh, while others are national or international studies involving multiple hospitals.

Research may be carried out by members of your baby's clinical care team or by dedicated research staff.

Is research safe?

All research carried out within the NHS must be reviewed and approved by an independent Research Ethics Committee.

These committees help protect the rights, dignity and wellbeing of patients and families.

Research studies only receive approval if:

- they are considered scientifically worthwhile
- the potential benefits outweigh any risks
- patient safety and wellbeing are prioritised.

Within NHS Lothian, studies are also reviewed by research governance teams to ensure they are safe and appropriately managed.

Your baby's safety and care will always remain the top priority.

How will we tell you about research opportunities?

If your baby may be eligible for a research study, a member of the clinical or research team may speak with you.

They will explain:

- the purpose of the study
- what taking part would involve
- any possible risks or benefits
- what information or samples may be collected
- whether there are any alternatives.

You will have the opportunity to ask questions and will be given time to decide whether you would like your baby to take part.

We understand that having a baby in the neonatal unit can be stressful and overwhelming. We will always try to approach families sensitively and at an appropriate time.

If you agree for your baby to take part, you will usually be asked to sign a consent form.

Research without prior written consent

Sometimes babies are eligible for studies shortly after birth or during emergency situations when treatment decisions must be made quickly.

In these situations, it may not always be appropriate or possible to discuss research in detail beforehand. Some studies may therefore use:

Deferred consent

Your baby may be enrolled into a study initially, and the research team will speak with you as soon as possible afterwards.

You will then be asked whether you are happy for your baby to continue in the study and for information already collected to be used.

Opt-out consent

For some studies, all eligible babies may be included unless parents choose not to participate.

Information about these studies may be included in admission information packs or discussed with families by the neonatal team. You can choose at any time that you do not want your baby to participate.

These approaches are only used in studies approved by ethics committees and where they are considered appropriate and safe.

How will my baby be identified for research?

Different studies have different eligibility criteria.

To identify whether your baby may be suitable for a study, members of the research team may review:

- your baby’s medical records
- pregnancy and birth records
- information collected as part of routine clinical care.

If you do not want research staff to review your baby’s records for study eligibility, please let a member of the neonatal team know.

Will my baby benefit from taking part?

Your baby may or may not benefit directly from taking part in a research study.

However, the information gained through research may help improve care and outcomes for future babies and families.

Some families also value the opportunity to contribute to improving neonatal care.

What if I do not want my baby to take part?

Taking part in research is entirely voluntary.

Your baby will receive the same high standard of care whether or not you decide to participate.

You are free to:

- decline participation
- ask further questions
- withdraw your baby from a study at any time.

You do not need to give a reason for your decision.

What happens to research results?

Results from research studies are often published in medical or scientific journals and may help shape future neonatal care.

Research findings are usually anonymous and will not identify individual babies or families.

Some studies may offer families the option to receive information about study results once they become available.

Confidentiality and data protection

Personal information collected during research studies is handled confidentially and in accordance with UK data protection laws.

Only authorised members of the research or healthcare team will have access to identifiable information.

Information used for analysis or publication is usually anonymised wherever possible.

Further information and support

If you have questions about a research study involving your baby, please speak to:

- your baby's nurse or doctor
- the neonatal research team
- the study team listed on the study information sheet.

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51 Little France Crescent
Edinburgh
EH16 4SA

Main reception: 0131 242 2601 / 0131 242 2602

Neonatal Research Team: 0131 242 2586

Email: loth.neonatalresearch@nhs.scot

For general hospital enquiries: 0131 536 1000

Useful organisations

Simpsons Special Care Babies (SSCB) A charity supporting babies, families and staff connected with the Simpson Neonatal Unit. Website: www.sscb.org	
Bliss A UK charity supporting premature and sick babies and their families. Website: www.bliss.org.uk	
NHS Research Scotland Information about health research in Scotland. Website: www.nhsresearchscotland.org.uk	

If you need this leaflet in another format or language, please speak to a member of staff.

Alternative formats may include:

- large print
- easy read
- braille
- audio
- translated versions.

It's OK to Ask

When you understand what's going on with your health, you can make better decisions around your care and treatment.

www.nhsinform.scot/campaigns/its-ok-to-ask/

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