

Read more about how we will process and protect you and your baby's data, on our website: [www.npeu.ox.ac.uk/ctu/privacy-notice](http://www.npeu.ox.ac.uk/ctu/privacy-notice)

Further information can also be found at Manchester University NHS Foundation Trust's website:

<https://research.cmft.nhs.uk/getting-involved/gdpr-and-research>

How to contact us	
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## Timing of Stoma Closure in Neonates (ToSCiN) Trial



### Parent Information Sheet (Parent): Example for Interviews

We are doing research to help us understand when the best time is to close (reverse) a baby's stoma. We are inviting you to take part because your baby has needed a stoma as part of his/her surgical treatment. Before you decide if you want to take part, it is important for you to understand why the research is being done and what it will involve for you and your baby.

#### Key Points

- We currently don't know when it is best for babies to have their stoma closed (reversed). Some research suggests it is better to do this earlier on, whereas some indicates it is better to do it later.
- The most reliable way to find out which is actually better for babies is to do a clinical trial comparing stoma closure at two different time points.
- In this project some babies will have their stoma closed around 6 weeks after it was made (early) and some babies will have it closed at about 12 weeks (late).
- All babies taking part will be monitored very closely.
- Your baby's participation in this study is completely optional. If you decide not to take part in the study or later change your mind about taking part, this will not affect the care your baby receives.

#### Why are we doing this study?

A key part of your baby's care moving forwards is to close the stoma so that your baby can poo normally from the bottom. Deciding when to do the operation to close your baby's stoma is difficult. Closing a baby's stoma may mean they can take more milk feed, may influence growth and may determine when they are ready to go home. However, closing a stoma too early may lead to problems during the operation or with healing afterwards, and may mean that a baby needs to stay in hospital longer. For

these reasons doctors and surgeons are uncertain when the best time to close a baby's stoma is.

The ToSCIN study aims to find out if it is better to close a baby's stoma early or later on. To do this, we need babies with stoma and their parents/carers to take part. The study is taking place in neonatal units across the UK. We hope to involve several hundred babies with a stoma.

### **What will happen to my baby if we agree to take part?**

If you agree to take part in the study we will use a computer to decide at random whether your baby will have their stoma closure surgery about 6 weeks after the stoma was made (early) or about 12 weeks after the stoma was made (late). The chance of having the surgery early or late is equal. The ONLY thing that will be different between the two groups will be the time at which the surgery is done. Your baby will be closely monitored to check on their progress. In particular we are interested to find out when they start feeding, how long they stay in hospital and if they have any problems after the operation. This will all be done routinely as part of your baby's standard care in the neonatal unit.

Both 'early' and 'late' operations are already routinely done in neonatal surgical centres in the UK. Taking part in this study will not expose your baby to treatments that do not already happen. The actual operation they receive and the surgeon that does this operation will be exactly the same as if they had not been involved.

### **Will my baby definitely get early or late closure?**

It is possible that once your baby is allocated to either 'early' or 'late' stoma closure this is actually not the best thing for them. For example if they are allocated to 'early' surgery but are not well enough at 6 weeks then the surgery may be delayed. Similarly, if they are allocated to a 'late' operation, but it is obvious that they would definitely benefit from an earlier operation (for example if they are having problems with their stoma), the surgery will be brought forward. Whether you take part in this study or not, the clinical team looking after your baby will monitor things closely and if required, change the timing or your baby's operation.

### **What are the potential benefits of taking part?**

It is impossible to say whether or not your baby will directly benefit from taking part as we do not know whether an early or late operation is better.

By taking part, you will be helping us to learn about how to treat children such as yours better in the future.

### **What will happen to the study results?**

At the end of the study the results will be published in a medical journal. You and your baby will not be identified in any report or publication. If you would like, we will send a summary of the results to you. They will also be available on the study website: [www.npeu.ox.ac.uk/toscin](http://www.npeu.ox.ac.uk/toscin).

### **Who is running the study ?**

The study is being run by the Manchester University NHS Foundation Trust and the National Perinatal Epidemiology Unit Clinical Trials Unit at the University of Oxford. All the doctors and researchers involved have experience of running studies like this involving babies like yours. The study is funded by The National Institute for Health Research (NIHR) which is the research arm of the NHS

### **What if something goes wrong?**

All research in the NHS is looked at an independent group of people to protect the interests of participants. This study has been reviewed by the XXXXX Research Ethics Committee. It is extremely unlikely that anything will go wrong. If at any stage you have any concerns about this study or the way it has been carried out, you can contact the people listed below. The normal National Health Service complaints mechanisms are also available to you. For NHS service advice or support please contact Patient Advice and Liaison Services (PALS) services. The charity Bliss can also provide a wide range of free services for the families of premature and sick babies, including emotional and practical support. They are supporting this research project and can be contacted via email: [hello@bliss.co.uk](mailto:hello@bliss.co.uk) or telephone: 020 7378 1122.

### **How we handle your personal information**

All information that we collect about you and your baby during the study will be kept confidential and stored securely. If you decide to take part, we will collect some personal information about you and your baby including name, address, contact details and baby's NHS number. This information will be sent to the Study Coordinating Centre at the University of Oxford.