



## Parent Information Sheet

### Pilot for the WHEAT study: Withholding enteral (milk) feeds around blood transfusion

#### What is the purpose of this study?

The WHEAT study will compare two different approaches, feeding babies or not feeding babies during blood transfusions, to work out which one is better. At the moment we don't know how best to feed babies during blood transfusions, some hospitals and doctors stop feeds while others don't.

This is important because babies that are born early often need blood transfusions because they become anaemic (they do not have enough red blood cells which can cause weakness or breathlessness). We know babies need blood transfusions but we do not know how best to look after them during the transfusion. Some babies who are born early can develop a bowel disease called necrotising enterocolitis (NEC) which can be serious and can have long-term effects on how babies grow and develop. We want to know if feeding babies or not feeding babies while they have a blood transfusion has an effect on the number of babies that get NEC.

Before we run the full WHEAT study we need to run a pilot study, this is a smaller test study. We need to do this because in the WHEAT study we plan to collect information directly from babies' electronic medical notes to make the study easier for the doctors and nurses looking after your baby. Collecting information from babies' electronic medical notes like this is a new approach, so we need to make sure collecting information in this way works. This is the purpose of the pilot study.

#### Why has my baby been chosen?

We are including all babies that are born before 30 weeks of pregnancy in the study.

#### Does my baby have to take part?

We are planning to include every eligible baby in the study unless you tell us you do not want your baby to take part. **The WHEAT study is an opt-out study. This means that all babies will take part unless you let a member of the neonatal team know that you do not wish your baby to participate.**

#### What do I do if I don't want my baby to take part?

If you don't want your baby to take in this study part please tell any member of the neonatal team.

#### What will happen if my baby does take part?

If your baby is taking part, when the doctors decide that your baby needs a blood transfusion and your baby is being fed milk, we will ask the team looking after your baby to do one of 2 things. Either to continue feeds as before, or to pause feeds for 4 hours before, during and 4 hours after the blood transfusion. The decision whether to feed or not around blood transfusions will be decided randomly for each baby, so each baby will have an equal chance of being fed or not around their blood transfusions. Once your baby has been allocated a treatment approach, this approach will be used for any transfusion they might need until they reach a gestation of 36 weeks'. All other day-to-day decisions about feeding and looking after your baby will be made by doctors and nurses caring for your baby.

Babies in the WHEAT study will not have any extra tests and your baby will be looked after in the same way as a premature baby not taking part in the study.

#### Will my baby definitely have a blood transfusion?

Not all babies born early need a blood transfusion, but most do and many need more than one. Being in the WHEAT study will not affect the number of transfusions your baby will have.

#### Are there any risks or side effects for my baby?

We don't think that there are any risks or side effects for your baby in taking part in the WHEAT study.

## Will my baby get hungry if feeds are withheld around blood transfusions?

We don't know when premature babies start to feel hungry. It is quite common for babies born early to have their feeds withheld for lots of reasons. When this happens, babies are given intravenous (IV) fluid or nutrition with sugar in it to ensure their blood sugar does not drop. Babies in the WHEAT study who are having their milk feeds stopped around a blood transfusion will be given IV fluid or nutrition with sugar in it in exactly the same way.

## Are there any benefits for my baby?

Both of the different approaches in the WHEAT study are currently acceptable to doctors but we don't know if one is safer. For babies not taking part in this study, it depends on the unit looking after your baby as to whether feeds are given or withheld around blood transfusions. Taking part in a neonatal research study may be beneficial for your baby.

## What if relevant new information becomes available?

If any information becomes available during the study that might make you change your mind about your baby's involvement we will tell you.

## Will my taking part in this study be kept confidential?

We will use your baby's medical records to collect some personal information about your baby, like name and date of birth; these details will be kept securely on NHS computers at Chelsea and Westminster Hospital for 25 years, and will only be seen by the study team to ensure that the study is carried out safely and correctly. For more information on how we process and protect your data, please see our website:

[www.npeu.ox.ac.uk/wheat/privacy-notice](http://www.npeu.ox.ac.uk/wheat/privacy-notice)

## What will happen to the results of the research study?

At the end of the study the results will be published in a medical journal. They will also be available on the trial website: [www.npeu.ox.ac.uk/wheat](http://www.npeu.ox.ac.uk/wheat) You and your baby will not be identified in any report or publication about the study.

## Who is organising and funding the research?

The study is being run by the National Perinatal Epidemiology Unit Clinical Trials Unit at the University of Oxford and sponsored by Imperial College London. The study is funded by the Medical Research Council (MRC), United Kingdom.

## Who has reviewed the study?

All research in the NHS is assessed by an independent group of people to protect the interests of participants. This study has been reviewed by the London-Bloomsbury Research Ethics Committee.

## What if something goes wrong?

It is extremely unlikely that anything will go wrong. However we are required by Imperial College to inform you that "in the unlikely event of your suffering serious and enduring harm or injury directly related to your participation in this study, you are eligible to claim for compensation through the Imperial College School of Medicine's "No Fault" Insurance Policy." If your baby is harmed due to someone's negligence, then you may have grounds for a legal action.

## What if there is a problem?

If at any stage you have any concerns about this study or the way it has been carried out, you should contact the Coordinating Centre or any of the contacts listed below.

**Thank you for reading this leaflet – please discuss this study with the doctor or nurse who is looking after your baby if you have any questions.**

### Coordinating Centre:

NPEU CTU  
01865 617923  
[wheat@npeu.ox.ac.uk](mailto:wheat@npeu.ox.ac.uk)

### Principal Investigator:

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### Joint Research Compliance Office:

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### PALS:

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