



Parent Information Sheet

Study Title: The WHEAT International Trial: Withholding enteral (milk) feeds around blood transfusion

This neonatal unit is taking part in a research study called **the WHEAT International trial** which is comparing practices that already take place in neonatal units across the UK. We plan to include every eligible baby in the study unless you tell us you do not want your baby to take part.

What is the purpose of this study?

The WHEAT International trial will compare two different approaches, feeding babies or not feeding babies during blood transfusions, to work out which one is better. Both approaches are standard practice in the UK but 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 changes the number of babies that get NEC. WHEAT is taking place in neonatal units across the UK and Canada and will involve about 4,500 babies across the UK and Canada.

Why has my baby been chosen?

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

Does my baby have to take part?

No. We are comparing practices that already take place in neonatal units across the UK and Canada and plan 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.**

If you do want your baby to take part in the WHEAT International trial, you don't need to do anything.

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

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

What will happen if my baby does take part (if I don't opt out for my baby)?

If your baby does take 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 two things (both of which are standard practice in the UK). 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 when they have 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 35 weeks. All other day-to-day decisions about feeding and looking after your baby will be made by the doctors and nurses caring for your baby.

Babies in the WHEAT International trial 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 International trial will not affect the number of transfusions your baby will have.

What are the possible disadvantages and risks of taking part?

There are no additional disadvantages/risks involved in taking part in this study. We are comparing two pathways of care that are standard practice.

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 International trial 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. In a small number of cases a new intravenous cannula, or "drip", might be needed when feeds are stopped around a blood transfusion, but this happens during some blood transfusions in or outside of the WHEAT International trial.

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.

What happens when the research study stops?

Once the treatment is complete the data from the study will be analysed and published. At the end of the study the results will be published in a medical journal and presented at medical conferences. They will also be available on the trial website (www.neoepoch.com/wheat-trial). You and your baby will not be identified in any conference presentation, report or publication about the study.

Where can you find out more about how your information is used

Details about how we use your information can be found at the end of this information sheet.

Who is organising and funding the research?

The study is being run by the Imperial Clinical Trials Unit at Imperial College and sponsored by Imperial College London. The study is funded by the Canadian Institute for Health Research, Canada. Researchers are not receiving payment or benefits over and above their normal salary. Research participants/their parents/carers will not receive any payments for taking part in this research.

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.

How will find out the results of the 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: <http://neoepoch.com/wheat-trial> You and your baby will not be identified in any report or publication about the study.

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.

Contact for Further Information

| Principal Investigator: | Chief Investigator: | Patient Advisory Liaison Service (PALS): |
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| XXXX XXXX XXXX | Dr Chris Gale Imperial College London 0203 315 3519 christopher.gale@imperial.ac.uk | XXXX XXXX XXXX |

HOW WILL WE USE INFORMATION ABOUT YOU?

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your baby's information and using it properly. Imperial College London will keep your baby's personal data for 25 years after the study has finished in relation to primary research data.

We will need to use information from your baby's medical records for this research project. This information will include your babies NHS number, name and date of birth.

People will use this information to do the research or to check your baby's records to make sure that the research is being done properly.

People who do not need to know who your baby is will not be able to see your baby's name or contact details. Your baby's data will have a code number instead.

We will keep all information about your baby safe and secure.

Some of your baby's information will be sent to Canada to be analysed for this study, but this information will not include your baby's name or contact details. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of your baby's data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree for your baby to take part in a research study, we will use your baby's data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](#)

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other

countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

In this study we will transfer some of your baby's information to Canada to be analysed. Where this information contains your baby's personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your baby's personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your baby's personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your baby's personal data for specified purposes and in accordance with our policies.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your baby's hospital notes. If you do not want this to happen, tell us and we will stop.
- We need to manage your baby's research records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your baby.

If you agree for your baby to take part in this study, you will have the option to take part in future research using your data saved from this study.

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 Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team'.

COMPLAINT

If you wish to raise a complaint on how we have handled your baby's personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your baby's personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.