

Opt-out consent guidance for the WHEAT trial

Use this as a guide when discussing the WHEAT Trial with parents. If you have any questions about the consent process, contact the trial team at WHEAT@imperial.ac.uk

IMPORTANT REMINDERS:

- You must provide the parent(s)/guardian(s) with a copy of the Patient Information Sheet (PIS)
- You must display the WHEAT trial poster in parent facing areas on your neonatal unit
- You must have received training on the trial procedures – speak to your PI or Research Nurse if you are unsure of any aspect of this trial

Conversation Guidance Points:

- The WHEAT trial is trying to find out how best to look after premature babies when they have a blood transfusion
- Premature babies often need a blood transfusion
- Some doctors think that pausing a baby's milk feeds around the blood transfusion reduces the risk of a disease called necrotising enterocolitis, but others think that it is safer to continue feeds
- Currently, we do not know whether it is better to pause feeds around blood transfusions or to continue feeds.
- About half of neonatal doctors pause feeds when a baby has a blood transfusion and about half continue feeding – we need a large research trial to find out which is best, this is what the WHEAT trial hopes to do
- Babies in the WHEAT trial will have an equal chance of having their feeds paused or continued around the time they get a blood transfusion – this is the only way to find out which of these approaches is better
- Babies in the WHEAT trial will have the same chance of having a blood transfusion as babies not in the WHEAT trial – the WHEAT trial is only looking at how babies are fed during blood transfusions
- Babies will not need any additional blood tests or medicines to be in the WHEAT trial

- Both of the approaches being compared in the WHEAT trial (pausing or continuing feeds around blood transfusions) are already commonly practiced in the United Kingdom – no new treatment is being tested – instead, we are just trying to work out which currently used approach is safer
- Babies commonly have their feeds stopped while in neonatal units for lots of different reasons and sometimes need intravenous fluid (IV) or nutrition with sugar. Some babies in the WHEAT trial who have their feeds paused around transfusion will be given IV fluid or nutrition in the same way, in a small number of cases a new IV cannula or ‘drip’ might be needed
- The WHEAT trial is an opt-out study – this means that all babies will take part unless you let us know that you do not want your baby to be part of the trial
- You can tell us that you do not want your baby to be part at any time
- We are trying to make the WHEAT trial as simple as possible so we will be taking all information for the trial directly from your baby’s electronic medical notes
- This means that there are no forms to sign – if you are happy for your baby to be in the WHEAT trial, we will record this in their medical notes

NEXT STEPS

1. Update the *Screening and Enrolment Log*
2. Update Badger with the trial opt-out consent outcome
3. Document this in EPR OR use the *Consent and Eligibility Labels* if your site uses paper notes
4. Place the *Eligibility Card* on the cot to alert the team to randomise when appropriate

Only randomise when the baby requires a blood transfusion (>4 hours before first transfusion)