

3. What is Opt-out Consent?

- **Opt-out consent is an informed way of including infants in research**
- **The aim is to make it easier for parents and infants to take part in research**
- **The parent information sheet makes it clear that opt-out consent is being requested**

Why Opt-out consent?

- **Both trial interventions are well established practices, that are already performed in hospitals across the UK**
- **There are no parent questionnaires and no follow up after discharge**
- **There are no trial medications to administer**

This trial is exploring a practice that is variable throughout UK hospitals, and where, outside the neoGASTRIC trial, the allocation is based on which hospital the baby is at or which person is looking after the baby. Instead of arbitrarily allocating practice, the neoGASTRIC trial is formally randomising the different care pathways so we can learn which pathway is optimal.

How does opt-out consent work in practice?

- **No need to discuss trial with parents**
 - But be available to discuss if parents/carers have questions
- **Only record in infants notes if parents opt-out**
 - It is optional to record that information has been given to parents

Key information to note with opt-out consent:

1. There **will not be a signed consent form** for the trial.
2. Infants, who are meeting the eligibility criteria and whose parents have **not opted out**, will be randomised and included in the trial.
3. Even though it is an opt-out consent trial, it's still important that parents/carers get the information they need to understand the trial to **make an informed decision**.
4. Study information leaflet should be provided to parents/carers of babies around the time of admission to the neonatal unit.
5. It is important for site staff to determine whether it is feasible for parent/carer to fully understand the opt-out consent process (language barrier, mental capacity etc.). If not, this should be noted in the infants' notes and the infant should not be recruited.
6. Please display the **neoGASTRIC poster and banner** in prominent places around your unit e.g. breastfeeding rooms, parent kitchen/break-out rooms, parental boards and corridors and reception areas.
7. Please also ensure that all site staff are acquainted with the trial information, in order to be able to answer questions and/or re-direct parents to neoGASTRIC site staff.

Parents will have the option to opt-out **if they do not want their infant randomised into the trial**. They just need to let you know and you can mark this in their notes.

They will have around 24-48 hours to do this in almost all cases, and in many cases a lot longer (given how long it takes for a baby to be established on feeds >15ml/kg/day for more than 24 hours in many neonatal units).