

What is it?

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

Why is it used?

Opt-out consent is often considered appropriate for observational studies especially where it relies on clinical data that is already being collected during routine care and taking part does not affect the care the baby receives.

How does opt-out consent work in practice?

- **Before a baby is enrolled, parents must be made aware of the study by being provided with the Parent Information Leaflet (PIL).**
- **Speak with the parents and answer any questions they may have.**
 - There is no need to have a detailed discussion about the study.
- **Document in the baby's medical notes whether they have been enrolled in the study or whether the parents have chosen to opt out.**

Key points to remember:

1. Aim to enrol eligible babies within 48 hours of birth.
2. There is no signed consent form.
3. Babies who meet the eligibility criteria and whose parents have not opted out should be included in the study.
4. Even though it is opt-out consent, it's still important that parents/carers get the information they need to understand the study to make an informed decision.
5. Information leaflets should be provided to parents/carers of babies around the time of admission to the neonatal unit.
6. 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 baby's notes and the baby should not be enrolled. Where available, the use of NHS interpreters should be considered.
7. Please display the BASE Observational Study poster in prominent places around your unit e.g. breastfeeding rooms, parent kitchen/break-out rooms, parental boards and corridors and reception areas.
8. Please also ensure that all site staff are acquainted with the study information, in order to be able to answer questions and/or re-direct parents to BASE Study site staff.