Verbal Consent

BASE study requires parents to provide **verbal consent**.

What is verbal consent?

Verbal consent means providing consent during a conversation. There is no requirement for the parent to complete a consent form, however, site staff are required to document verbal consent on the form provided on their behalf and file in the baby's medical notes.

Parents of eligible infants must provide consent verbally for their infant to participate in the study. This must happen prior to randomisation. Documentation that a parent (see below 'who can provide consent' has provided consent must be recorded in the infant's medical notes and once the infant has been randomised, another copy filed in e-ISF.

Who can take consent and when?

Verbal consent can be taken by a trained and delegated individual (recorded on the delegation log). Verbal consent may be sought when a baby is between 23^{+0} and 30^{+6} weeks^{+days} of gestation inclusive, even before they have developed metabolic acidosis. Information about the study can be provided to potential parents antenatally, however, verbal consent must be confirmed once the baby has been born.

Who can provide consent?

Legal parental responsibility is defined as either:

- mother
- Father/partner who Is married or in a civil partnership with the child's mother

Steps to follow after parent has provided verbal consent

1. Complete the documentation of verbal consent form (provided in the Document Box) and file in the infant's medical notes. Place the 'Eligible' cot card next to the infant's cot.

2. If the infant is eligible/becomes eligible, please progress to randomisation (Please see **Guidance Sheet: Randomisation**)

3. When the infant has been randomised, ensure the documentation of verbal consent form (provided in the Document Box) has been completed and file in the infant's medical notes and ISF. Put the relevant 'trial allocation' cot card in the baby's cot and the sticker in the infant's notes (both provided in the Document Box).

GUIDANCE SHEET

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Completing the documentation of verbal consent form

- Documentation of verbal consent forms are provided in the Document Box.
- The form must be wet signed by person who observed parent's consent.
- If parent provides consent before infant develops metabolic acidosis, file in the baby's medical notes. Once randomised, add study number to the form, and scan and save a copy in your ISF too.

What to do if a parent declines participation?

Please ensure the 'NOT IN' cot card (provided in the Document Box) is placed clearly by the baby's cot so all staff are aware and do not approach the parents again. Please document on the screening log that the baby will not be included in the BASE study. This should also be documented in the baby's medical records.

For detailed information on withdrawals, please see **Guidance Sheet: Withdrawals**.

GUIDANCE SHEET