7. Withdrawal/Discontinuation

GUIDANCE SHEET 7

Once an infant has been randomised into the trial, at any point and for any reason, a parent/carer can request to opt out of the trial.

The following events **do not** constitute a withdrawal:

- If an infant allocated to the *No routine measurement of gastric residual volumes* care pathway has developed a condition for which regular gastric residual measurement is clinically indicated.
  - → This situation is captured on the Daily Feed Log. When regular gastric residual measurement is no longer clinically indicated, the infant should be allocated back to their randomised care pathway if this is considered clinically appropriate.
- If an infant has been randomised in error (for instance, they are found not to be eligible) contact the neoGASTRIC Coordinating Centre (NPEU CTU) to discuss next steps **before completing any withdrawal form or discussing with parents/carers.**

Withdrawal/Discontinuation Process

Parents/carers have the right to withdraw their infant from the study at any time.

When a parent expresses a wish to withdraw their infant from the study:

1. If deemed appropriate, the clinical team should make time to discuss any potential concerns or misconceptions related to withdrawal.
2. Record the decision on the Withdrawal and discontinuation eCRF on OpenClinica and within the infant's medical notes.
3. The reason for their decision should be detailed in the "Further Information" section, if it has been provided.

   ! Remember that parents do not have to provide any reason for their withdrawal and should not feel any obligation to do so.
4. Ask permission for the study team to complete data collection after reverting to standard care using infant's medical records and to carry out indirect (no contact with participant) for long-term follow-up using routine national databases. It is still useful for the trial to collect data even if the infant has been discontinued from their allocated pathway.

   If they agree to ongoing data collection this does not constitute a withdrawal, but a **discontinuation of the allocated trial pathway.**
5. Reassure them that withdrawal or discontinuation of allocated pathway will not affect their infant's ongoing clinical care or their care in hospital.

   However, data collected up to the point of withdrawal will be used in the study.

If a clinician wishes to withdraw or discontinue the allocated pathway of an infant in the best interest of the infants' health, the same procedure detailed above should be followed.

If you are unsure whether a Withdrawal form needs to be completed, contact the trial Coordinating Centre in the first instance to discuss.