

Once an infant has been randomised and a study number allocated, they are entered into the study. After this, at any point and for any reason, a parent or clinician may decide to withdraw an infant from the study.

The following events do not constitute as withdrawal:

- not administering IMP to infants randomised to Early Surfactant Therapy
- administering IMP to infants randomised to Expectant Management

These are captured on the CRFs in Openclinica.

Withdrawal Process

Parents will have the right to withdraw their infant from the study at any time. When a parent expresses a wish to withdraw their infant, undertake the following steps:

- If deemed appropriate, the clinical team should make time to discuss any potential concerns or misconceptions related to withdrawal.
- Ask for permission for the study team to complete data collection using **infant's and mother's medical records** and indirect (no contact with participant) **long-term follow-up using routine national databases when the infant reaches one year of age**, corrected for prematurity.
- Where possible, record the reasons for withdrawal, for e.g, clinical decision or any other decision. The parent should be clearly informed that they are under no obligation to provide a reason for withdrawal
- Reassure them that withdrawal from the study 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.
- Check if the parent would like to receive results at the end of the study

If the mother wishes to only withdraw herself from completion of the Mother's questionnaire, record this in the medical notes and do not provide her with subsequent questionnaires.

Record the information within the **Withdrawal Form in Openclinica and within the infant's medical notes.**

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