

GUIDANCE SHEET 8: Withdrawal

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 remove an infant from the study.

Definitions:

Discontinuation of intervention: by parental or clinician choice, the study intervention (in this case the lumbar puncture (LP) done by the method allocated by randomisation) is stopped, but data continues to be collected and analysed on an intention-to-treat basis. This will be recorded on the Procedure Form within OpenClinica.

Where an LP is performed, but the procedure deviates from the allocated technique, this should be recorded, either on the paper Lumbar Puncture / Lab Results Log for entry later or directly onto the OpenClinica Procedure Form. This **does not constitute a withdrawal**, and should not be reported as an Incident.

Withdrawal: usually by parental choice, the trial procedures (study intervention and/or data collection) are stopped for that infant. This should be recorded on a Withdrawal Form.

NB: The clinical decision on whether or not to have an LP or a repeat LP, should be made independently of any decision whether to continue the study intervention.

Reassure parents that trial participation or withdrawal does not affect the clinical decision whether further lumbar punctures are indicated.

Parental decision:

As per Good Clinical Practice (GCP), should a parent wish to remove their infant from the study, they may do this at any point without giving a reason. This will not impact on the family's future care.

When a parent expresses a wish to withdraw their infant, if deemed appropriate, the clinical team should make time to discuss any potential concerns or misconceptions. The parent(s) should be clearly informed that they are under no obligation to provide a reason.

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Parents should be asked whether they consent to the local team continuing to collect data on their infant until discharge and passing this on to the study team.

Infant withdrawal should be recorded as soon as possible on the Withdrawal Form on OpenClinica and within the medical notes. The infant's Consultant should be informed.

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