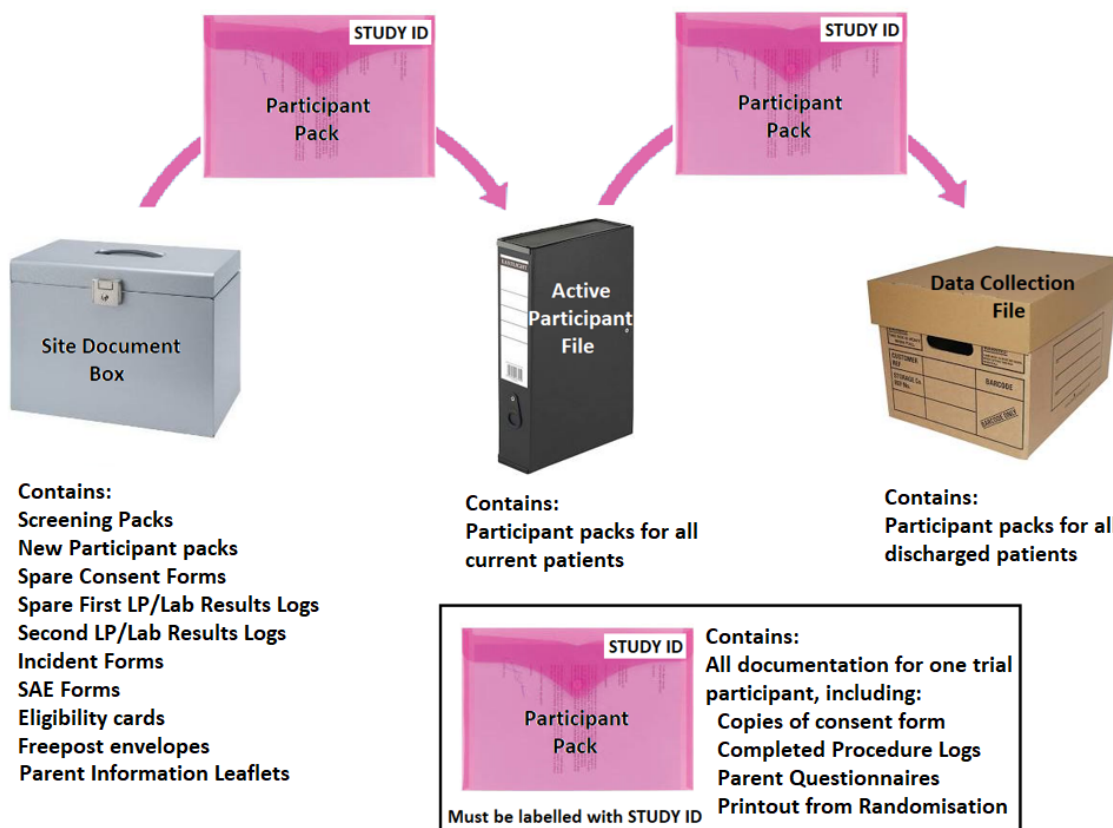


# GUIDANCE SHEET 5: Procedure Documentation

## NeoCLEAR Guide to filling out the Case Report Forms (CRFs)

If you have **not had OpenClinica training**, please fill in the **paper logs** (First LP Procedure / Lab Results Log and Second LP Procedure / Lab Results Log) and file these in the Participant Pack. Keep all Participant Packs in the Active Participant File so that they can be entered onto OpenClinica by a delegated individual. Logs may be filed in the clinical notes once all data entry is complete.



GUIDANCE SHEET 5

# GUIDANCE SHEET 5: Documentation

## Definitions:

For the purpose of NeoCLEAR, the following definitions apply:

A *procedure* is defined as a lumbar puncture involving one operator in one episode, but can include up to two attempts.

An *attempt* is defined as an instance of skin puncture. The needle can be readjusted after passing through the skin.

*Current indication* refers to the episode of illness for which the infant is undergoing a lumbar puncture.

*Persistent respiratory deterioration* = requiring escalation of respiratory support e.g. starting low flow, low flow switched to high flow, high flow to CPAP/BiPAP or intubation)

## Electronic Case Report Forms (eCRFs) and OpenClinica

All patient data for NeoCLEAR must be entered online to OpenClinica by a **delegated** individual (usually the local research nurse). Information must be filled in completely and accurately.

If you are experiencing difficulties with OpenClinica, please refer to the training podcasts on the NeoCLEAR website or contact the NeoCLEAR team on [neoclear@npeu.ox.ac.uk](mailto:neoclear@npeu.ox.ac.uk)

If you have had OpenClinica training, please log in and complete the following forms:

### Trial Entry Form

Please fill out this form once for each participant.

### First Lumbar Puncture form

Please fill this form out for each infant's **FIRST** NeoCLEAR lumbar puncture.

Practitioners who have not had OpenClinica training should fill out a paper log (available in Participant Packs, spares in Site Document Box) and data should be entered onto OpenClinica by a **delegated** individual. *Completed logs should be filed in the Participant Pack in the Active Participant File until they have been entered onto OpenClinica.* Once data entry is complete, these can be filed in the patient's medical notes.

If the infant has been randomised and the LP did not take place, the First Procedure Form must still be completed.

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## Second Lumbar Puncture Form:

Please use this form to enter details about **SECOND PROCEDURES ONLY**.

If the second LP was planned and did not take place, please provide details in the first section of the Form, then skip to the 'notes' tab to complete and save the form.

*Practitioners who have not had OpenClinica training should fill out a paper log (available in Site Document Box) and data should be entered onto OpenClinica by a **delegated** individual.*

## Parent Questionnaire Form

Please enter the results of the paper Parent Questionnaire exactly as they appear on the form. Any free text should be added exactly as written by the participant. Each consenting participant should have a first and a second Parent Questionnaire. Once entered onto OpenClinica, paper forms must be sent to the Trial Coordinating Centre via nhs.net email or freepost envelope.

If parents decline to complete the Parent Questionnaire, change the status of the form on OpenClinica to 'skipped':

- Click 'view/enter data'
- Click 'edit study event'
- Change 'status' to 'skipped'
- Click 'submit changes'

## Transfer Form:

Please complete this form each time the infant is transferred and when the infant is discharged or dies. The recruiting centre remains responsible for obtaining outcome data.

The transfer pack (continuing care guidance sheet and a copy of the Serious Adverse Event (SAE) form) should remain with the infants with all transfers.

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## Discharge Form:

**Please complete this form for each infant at discharge or death.**

Where antibiotic length is requested, this refers to all antibiotics for this episode of illness only. Please give the start and end date for all antibiotics, even if antibiotics were changed.

*Example 1:* A term baby is started on benzylpenicillin and gentamicin shortly after birth on 8/3/2018, undergoes an LP 3 days later, after which antibiotics are changed to cefotaxime and amoxicillin for 2 weeks. The infant finishes antibiotics on 22/3/2018. Dates of antibiotics relating to the episode of illness where the NeoCLEAR LP was performed should be entered as 8/3/18 to 22/3/18.

*Example 2:* A preterm baby is started on benzylpenicillin and gentamicin at birth on 3/1/2018, found to have a CRP rise, undergoes a NeoCLEAR LP and antibiotics are kept the same and given for 5 days until 8/1/2018. In an unrelated episode 3 weeks later, the baby has 48 hours of gentamicin and flucloxacillin.

Dates of antibiotics **relating to the episode of illness where the NeoCLEAR LP was performed** should be given as 03/01/2018 to 08/01/2018.

## Withdrawal forms:

Please complete this form only if an infant is withdrawn from the trial.

As per good clinical practice (GCP) guidance, parents do not need to specify reasons for withdrawal, so should not feel pressurised to do so.

## Serious Adverse Event (SAE) form:

Please only complete this form if an SAE has occurred. (See Guidance Sheet 6: Safety & Incident Reporting)