GUIDANCE SHEET 7: Continuing care

This form must be completed by the clinical research team **prior to an infant's transfer to another hospital**. It provides information for staff at the receiving hospital and must be transferred with the infant.

NeoCLEAR is a 2 x 2 factorial randomised controlled trial comparing the effect of lying vs sitting position and early vs late stylet removal on success rate for neonatal lumbar puncture (LP).

Infant's Name:	
Study ID:	
Date of most recent NeoCLEAR LP:	
Time (24hr clock) of most recent NeoCLEAR LP:	
Hospital where NeoCLEAR LP(s) took place:	
Contact name for local research team: (Research Nurse or Principal Investigator)	
Contact number for local research team: (in hospital where LP(s) took place)	

When the infant is discharged from the neonatal unit, please inform the recruiting site, who may ask for more information such as length of antibiotic courses and the date of discharge.

As long as the infant remains well, participating in NeoCLEAR should not affect their ongoing care. **They should be monitored for Serious Adverse Events (SAEs) until they are discharged home.**

GUIDANCE SHEET 7

GUIDANCE SHEET 7: Continuing care

Serious adverse events

Should the infant become unwell, you will be required to report some serious adverse events to the study team. A serious adverse event is any untoward medical occurrence which:

- Results in death
- Is life-threatening
- Requires participant hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Is an important medical event

The term ‘life-threatening’ refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event that, hypothetically, might have caused death if it were more severe. Medical and scientific judgement should be exercised in deciding whether an adverse event is serious.

The term ‘severe’ is often used to describe the intensity (severity) of a specific event; the event itself, however, may be of relatively minor medical significance. This is not the same as ‘serious’, which is based on participant/event outcome or action criteria usually associated with events that pose a threat to a participant’s life or functioning.

Reportable SAEs

REPORT any of the following Serious Adverse Events (SAEs), if suspected until the infant is discharged home:

- Iatrogenic meningitis
- Iatrogenic haemorrhage: spinal haematoma (symptomatic), intraventricular, intracerebral and subarachnoid haemorrhage
- Cerebral herniation
- Nerve damage

Expected SAEs

Other serious adverse events which may be expected in the study population are listed below. These **DO NOT NEED REPORTING UNLESS THOUGHT TO BE CAUSED BY LUMBAR PUNCTURE**:

- Anaemia
- Clinically significant intracranial abnormality on cranial ultrasound scan – intracranial haemorrhage or white matter injury
- Chronic lung disease / Broncho pulmonary dysplasia
- Coagulopathy requiring treatment
- Death (unless related to LP technique)
- Difficulty establishing enteral feeding
- Failed LP resulting in prolonged hospitalisation
- Hyperbilirubinemia (jaundice)
- Hypoglycaemia
- Hypotension
- Hypoxic ischaemic encephalopathy
- Low sodium level/hyponatremia
- Non-iatrogenic meningitis
- Necrotising enterocolitis
- Patent ductus arteriosus
- Pneumothorax or air leaks
- Pneumonia
- Pulmonary haemorrhage
- Pulmonary hypertension requiring treatment
- Respiratory failure
- Retinopathy of prematurity
- Seizures
- Sepsis / infection
- Thrombocytopenia

Unforeseeable Serious Adverse Events

An unforeseeable SAE is any event that meets the definition of a SAE and is not detailed in the list above as expected. **All unforeseeable SAEs that occur after consent until discharge home must be reported** (as detailed below).

How to report an SAE

SAEs must be reported as soon as possible after becoming aware of the event. Anyone can report an SAE.

To report a SAE:

1. Complete Paper SAE form located in Site Document Box and:
    - Email from an nhs.net account to orh-tr.NeoCLEAR@nhs.net OR
    - Fax to the NeoCLEAR Coordinating Centre on **01865 289740**.
2. By telephone direct to the NeoCLEAR Coordinating Centre on **01865 289278** (within office hours) or **0800 138 5451** (out of hours).

The SAE form may be faxed or emailed without the causality assessment.

If faxed or emailed, the person reporting the SAE must ensure the NeoCLEAR Coordinating Centre is aware of the SAE and check that they have received the form by telephoning the NeoCLEAR Coordinating Centre on **01865 289278** within office hours. The NeoCLEAR Coordinating Centre will confirm receipt of the SAE via telephone or email on the next working day.

Should you require any further information or have any other concerns or queries please email the NeoCLEAR Coordinating Centre during office hours on **01865 289278**.