Protocol ID: _____
Study Name: _____
Site: _____
Event Name: _____
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____
Interview Date:_____

NeoCLEAR Entry Form - v1.0

Section Title: Entry

Instructions: 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 this episode of illness.

Question B3: If the baby has had a lumbar puncture previously for a separate reason or episode of illness this should be answered as 'yes'. If the baby is having a repeat lumbar puncture because a previous lumbar puncture for the same reason failed, this must be answered as 'no'.

A1 What is the infant's date of birth? (dd-Mon-yyyy)

A2 What was the infant's estimated gestational age at birth (can be estimated clinically if unknown antenatally)?

○ 22	weeks	+	○ 0	days
○ 23			○ 1	
○ 24			○ 2	
○ 25			○ 3	
○ 26			○ 4	
○ 27			○ 5	
○ 28			○ 6	
○ 29				
○ 30				
○ 31				
○ 32				
○ 33				
○ 34				
○ 35				
○ 36				
○ 37				
○ 38				
○ 39				
○ 40				
○ 41				
○ 42				
○ 43				
○ 44				

A3 What is the infant's sex?

- ○ Male
- ○ Female
- ○ Indeterminate

A4 What is the infant's current working weight? (g)

A4.1 What was the infant's birth weight? (g)

A5 Do you have written consent for the infant's participation from the parent/legal guardian?
- Yes
- No

A6 Is the infant clinically stable to have a lumbar puncture at the time of randomisation?
- Yes
- No

A7 Is this the first lumbar puncture for the current indication?
- Yes
- No

A8 Is the infant intubated?
- Yes
- No

A9 Is the infant able to be held in a sitting position?
- Yes
- No

A10 Has the infant already been randomised into this trial?
- Yes
- No

A11 Was the infant one of a multiple pregnancy?
- Yes
- No

A11.1 How many infants were born?

A11.2 What was the birth order of this infant?

Has a sibling from this pregnancy already been recruited into this trial?
- Yes
- No

Please enter one of their study numbers

Randomisation

B1 Allocation for this infant
- Sitting position and early stylet removal
- Sitting position and late stylet removal
- Lying position and early stylet removal
- Lying position and late stylet removal

B2 Is the infant on antibiotics at time of randomisation?
- Yes
- No

B3 Has the infant had any previous lumbar punctures outside the trial?
- Yes
- No

Please give details of most recent lumbar puncture before the trial

Date of most recent lumbar puncture before the trial (dd-Mon-yyyy)

Was CSF obtained and sent to lab?
- Yes
- No

If CSF result obtained please give:
RBC count (10^6/L or per mm3 or per microlitre)

WBC count (10^6/L or per mm3 or per microlitre)

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Section Title: Baseline Assessment

Instructions:

C1. What is the primary indication for lumbar puncture? (please tick all that apply)

- ☐ Raised CRP
- ☐ Risk factors for sepsis
- ☐ Clinical signs of sepsis (e.g. fever)
- ☐ Abnormal blood white cell (or neutrophil) count or morphology
- ☐ Specific signs of meningitis (or encephalitis)
- ☐ Neurometabolic investigation
- ☐ Therapeutic (raised intracranial pressure)
- ☐ Other If Other, please specify

Protocol ID: _____

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Interview Date:_____

Section Title: Notes

Notes