

Protocol ID: \_\_\_\_\_

Study Subject ID: \_\_\_\_\_

Study Name: \_\_\_\_\_

Interviewer Name: \_\_\_\_\_

Site: \_\_\_\_\_

Interview Date: \_\_\_\_\_

Event Name: \_\_\_\_\_

Event Date: \_\_\_\_\_

**NeoCLEAR Lumbar Puncture /Lab Results Form - v1.0****Section Title: Practitioner**

Instructions: Please fill this form out for each infant's FIRST NeoCLEAR lumbar puncture. If the infant requires a second procedure, please use 2nd Lumbar Puncture / Lab Results Event. NB: 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.

A1 What is the infant's date of birth?

(dd-Mon-yyyy)

A2 Did the planned lumbar puncture  
procedure take place? ☐ Yes ☒ ?  
☐ No

Name of clinician who carried out  
the lumbar puncture procedure:

Reason lumbar puncture did not  
take place? ☐ Clinical instability (infant too unwell to proceed)  
☐ Clinical decision (LP no longer required)  
☐ Parent withdrew infant from lumbar puncture procedure  
☐ Other

Other, please specify

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**Section Title: Infant**

Instructions: **If the planned lumbar puncture procedure did not take place, please skip to the final section and Mark the CRF as complete**

- B1 What was the baby's respiratory status immediately before the lumbar puncture?
- ☐ Self-ventilating in air  
☐ Low flow oxygen (<2L/min)  
☐ High flow oxygen/air (≥2L/min)  
☐ CPAP/BiPAP

- B2 Has the infant had any previous intraventricular haemorrhage (IVH) before the lumbar puncture?
- ☐ Yes  
☐ No  
☐ Not scanned

What was the date the IVH was last seen on a scan? (dd-Mon-yyyy)

- What was the grade of IVH at that scan?
- ☐ Grade I   
☐ Grade II  
☐ Grade III  
☐ Grade IV

- B3 Has the infant received treatment for coagulopathy within the 24 hours before the LP? (i.e. FFP/cryoprecipitate/vitamin K) - not including routine prophylactic vitamin K given at birth
- ☐ Yes  
☐ No


B4. Does the infant have any current confirmed or probable infection at the time of lumbar puncture (tick all that apply):

☐ None of the below

☐ NEC 

☐ Pneumonia

☐ Sepsis 

☐ Blood culture positive 

☐ Urine infection 

☐ Line infection

☐ Other Other, please specify

- B5 Has a blood test been performed since birth?
- ☐ Yes  
☐ No

(dd-Mon-yyyy)

Date of latest blood test before the procedure:

Platelets	(x10 <sup>9</sup> /L)	<input type="checkbox"/> No results available
WBCs	(x10 <sup>9</sup> /L)	<input type="checkbox"/> No results available
Neutrophils	(x10 <sup>9</sup> /L)	<input type="checkbox"/> No results available
RBCs	(10 <sup>12</sup> /L)	<input type="checkbox"/> No results available
C-Reactive Protein (CRP)	(mg/L)	<input type="checkbox"/> No results available

If CRP test date different from above, please enter date (dd-Mon-yyyy)

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**Section Title: Procedural details**

Instructions: Attempt is defined as the needle passing through the skin

**If the planned lumbar puncture procedure did not take place, please skip to the final section and Mark the CRF as complete**

C1 What was the date & time of the procedure? (dd-Mon-yyyy) Time (hh.mm [24 hr])

**C2. Which type(s) of sedation and analgesia did the infant receive? (Please tick all that apply)**☐ None ?☐ Non-nutritive sucking☐ Oral sucrose/dextrose/glucose☐ Milk☐ Topical local anaesthetic☐ Paracetamol☐ NSAID☐ Opiate☐ Chloral hydrate☐ Midazolam☐ Other Other, please specify**Lumbar puncture details**

C3 How many attempts were there in this procedure? ?

Give details of LP attempts				
Attempt no.	Technique used	Other, please specify	Appearance of best sample for each attempt?	Sample sent to lab?
	<input type="radio"/> Lying and LSR <input type="radio"/> Lying and ESR <input type="radio"/> Sitting and LSR <input type="radio"/> Sitting and ESR <input type="radio"/> Other		<input type="radio"/> No sample obtained <input type="radio"/> Blood only <input type="radio"/> Blood-stained CSF <input type="radio"/> Pure CSF obtained	<input type="radio"/> Yes <input type="radio"/> No

☐ Yes☐ No


C4 Was the technique used (in any of the attempts) different to the technique allocated at randomisation?

Please specify the reason for the change in technique

- ☐ Clinical decision  
☐ Parental decision  
☐ Other

Give any further details why technique different to allocation


C5 What was the infant's level of struggling movement during the needle insertion for the 1st attempt?

- ☐ None (0)   
☐ Mild (1)  
☐ Moderate (2)  
☐ Severe (3)

The following questions are from start of cleaning skin to end of all attempts (C6-C9)

C6 How long did the procedure take? (mins)  (sec)

C7 What was the infant's lowest oxygen saturation? (%) 

C8 What was the infant's lowest heart rate? (bpm) 

C9 What was the infant's highest heart rate? (bpm) 

C10 Were there any immediate complications with the lumbar puncture?

- ☐ None  
☐ Procedure abandoned due to cardiorespiratory deterioration  
☐ A persistent respiratory deterioration requiring an escalation of respiratory support within 1 hour of the LP  
☐ Other



Other, please specify



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**Section Title: Lab Results from CSF**

Instructions: **If the planned lumbar puncture procedure did not take place, please skip to the final section and Mark the CRF as complete**

☐ Please check this box if no sample was sent to lab

D1 What was the lab reported appearance of the CSF?

- ☐ Clear/Yellow/Cloudy/Straw coloured  
☐ Pure blood/Clotted blood  
☐ Blood-stained/Bloody/Pinky  
☐ Other

Other, please specify

D2 Was microscopy performed?

- ☐ Yes  
☐ No

Date microscopy samples processed or reported

(dd-Mon-yyyy)

Time:

Reason no microscopy performed

- ☐ Sample clotted  
☐ Sample insufficient  
☐ Other

Other, please specify

**Lab results**

WBC (per mm<sup>3</sup> or per µl or 10<sup>6</sup>/L)

Neutrophil / PMN count (per mm<sup>3</sup> or per µl or 10<sup>6</sup>/L)


Lymphocyte count (per mm<sup>3</sup> or per µl or 10<sup>6</sup>/L)

RBC count (per mm<sup>3</sup> or per µl or 10<sup>6</sup>/L)

Gram stain

- ☐ Sample not analysed  
☐ No organisms seen  
☐ Organisms seen

D3 Based on the lab results is a 2nd procedure planned?

- ☐ Yes   
☐ No

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**Section Title: Notes**

Notes