

Protocol ID: _____

Study Subject ID: _____

Study Name: _____

Interviewer Name: _____

Site: _____

Interview Date: _____

Event Name: _____

Event Date: _____

NeoCLEAR 2nd Lumbar Puncture / Lab Results Form - v1.0**Section Title: Practitioner**

Instructions: Please use this form to enter details about SECOND PROCEDURES ONLY. For first procedures, please enter the first Lumbar Puncture / Lab Results Event. 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 second lumbar
puncture procedure take place?

☐ Yes☐ No

Name of clinician who carried out
the second lumbar puncture
procedure:

Reason second 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

Protocol ID: _____

Study Subject ID: _____

Study Name: _____

Interviewer Name: _____

Site: _____


Interview Date: _____

Event Name: _____

Event Date: _____

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 Has the infant had any intraventricular haemorrhage (IVH) since the 1st 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

B2 Has one of the following BLOOD tests been performed since the First Lumbar Puncture - Platelets, WBCs, Neutrophils or RBCs?

☐ Yes 

☐ No

Date of blood test(s)

Platelets (x10⁹/L) ☐ No results available

WBCs (x10⁹/L) ☐ No results available

Neutrophils (x10⁹/L) ☐ No results available

RBCs (10¹²/L) ☐ No results available

Protocol ID: _____

Study Subject ID: _____

Study Name: _____

Interviewer Name: _____

Site: _____

Interview Date: _____

Event Name: _____

Event Date: _____

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 completeC1
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? (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

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

- ☐ Yes
☐ No

Please specify the reason for the change in technique

- ☐ Clinical decision
☐ Parental decision
☐ Other

Give any further details why technique different to allocation

The following questions are from start of cleaning skin to end of all attempts (C5-C7):

C5 What was the infant's lowest oxygen saturation?

(%) ?

C6 What was the infant's lowest heart rate?

(bpm) ?

C7 What was the infant's highest heart rate?

(bpm) ?

C8
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

Protocol ID: _____

Study Subject ID: _____

Study Name: _____

Interviewer Name: _____

Site: _____

Interview Date: _____

Event Name: _____

Event Date: _____

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/Pink
☐ 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 resultsWBC (per mm³ or per µl or 10⁶/L)Neutrophil / PMN count (per mm³ or per µl or 10⁶/L)Lymphocyte count (per mm³ or per µl or 10⁶/L)RBC (per mm³ or per µl or 10⁶/L)

Gram stain

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

Protocol ID: _____

Study Subject ID:_____

Study Name: _____

Interviewer Name:_____

Site: _____

Interview Date:_____

Event Name: _____

Event Date: _____

Section Title: Notes

Notes