

# GUIDANCE SHEET 3: Randomisation

## Prior to Randomisation

- Ensure written informed consent has been obtained (see Guidance Sheet 2)
- Decide which practitioner will perform the procedure, where practicable.
- Ensure that the nominated practitioner is NeoCLEAR trained.

## Randomisation

The randomisation programme will allocate the infant to a technique and assign a Study ID number.

Access the online randomisation website at: <https://rct.npeu.ox.ac.uk/neoclear> or via the NeoCLEAR NPEU website <http://www.npeu.ox.ac.uk/neoclear> and select the 'Randomisation Link':



NEOCLEAR  
Optimising lumbar punctures  
in newborns

### Randomisation Program

If you need to contact us **urgently** with randomisation problems, please click on this [link](#)

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### Login

Centre:

Username:

Password:

Select centre and enter the site login details. These are found inside the lid of the Site Document Box.

Once logged in, select 'enter infant'.

Enter the infant's details into the Randomisation Tool. The named person completing the form needs to be on the Delegation Log for consenting and randomisation.

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## Section A: Eligibility

Time of randomisation: 3 May 2018 11:30

A1. What is the infant's date of birth?	07 ▼ / March ▼ / 2018 ▼
A2. What was the infant's estimated gestational age at birth?	33 ▼ weeks + 4 ▼ days
A3. What is the infant's sex?	Male ▼
A4. What is the infant's current working weight?	1850 g
A5. Do you have written consent for the infant's participation from the parent/legal guardian?	Yes ▼
A6. Is the infant clinically stable to have a lumbar puncture at the time of randomisation?	Yes ▼
A7. Is this the first lumbar puncture for the current indication?	Yes ▼
A8. Is the infant intubated?	No ▼
A9. Is the infant able to be held in a sitting position?	Yes ▼
A10. Has this infant already been randomised into this trial?	No ▼
A11. Was the infant one of a multiple pregnancy?	No ▼
Name of person completing this form:	Jane Doe
	Continue
	Cancel

When the information is complete, click 'continue'.

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Logged in as: Centre 1

**Section A: Eligibility**

Time of randomisation: 3 May 2018 11:30

Press **Complete** to confirm randomisation or **Amend** to change any values

**Complete** **Amend** **Cancel**

**A1.** What is the infant's date of birth? 07 / March / 2018

**A2.** What was the infant's estimated gestational age at birth? 33 weeks + 0 days

**A3.** What is the infant's sex? Male

**A4.** What is the infant's current working weight? 1850 g

**A5.** Do you have written consent from the parent/legal guardian? Yes

**A6.** Is the infant clinically stable to have a lumbar puncture at the time of randomisation? Yes

**A7.** Is this the first lumbar puncture for the current indication? Yes

**A8.** Is the infant intubated? No

**A9.** Is the infant able to be held in a sitting position? Yes

**A10.** Has this infant already been randomised into this trial? No

**A11.** Was the infant one of a multiple pregnancy? No

Name of person completing this form: Jane Doe

**If correct, click 'complete'**

**If incorrect, click 'amend' and correct data**

Home

**Check that the information entered is correct.** If any of the information is incorrect, click 'amend' and enter the corrected information before clicking 'complete'.

This will generate a study number and allocation.

Print two copies of the study allocation by clicking the 'print' link. File one copy in the participant pack. Take one copy to the procedure, which will be filed in the patient notes post-procedure.

Logged in as: Centre 1

**Section B: Randomisation**

NeoCLEAR study number:  
**13659**

Allocation  
**Lying position and late stylet removal**

Date and time of randomisation  
**03/05/2018 11:30**

Please enter the study number **13659** and allocation (**Lying position and late stylet removal**) on Form 1: Trial Entry immediately.

Please press the **Print** button below to generate a pdf which should be printed.  
The printout should be taken to the procedure and may be stored in the Trial Site File (it should not be filed in the infant's notes).

**Print**

Thank you for entering this infant into the NeoCLEAR study.  
Please click the link below to log out

**Log out**

**Enter the study number onto each page of the infant's trial documentation.**

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## Technical Difficulties

If you experience technical difficulties with internet access or the Randomisation website:

- During **normal office hours** contact the **NeoCLEAR Coordinating Centre** on **01865 289278**.
- **Out of hours** contact **0800 138 5451** and ask them to randomise on your behalf.

You will be asked to provide information on:

- The name of the trial (NeoCLEAR)
- Your name and phone number
- Site name/hospital

You will be asked three questions by the out of hours service:

1. Is your call about randomisation or allocation?
2. Is your call about emergency unblinding?
3. Or is this about another issue?

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