GUIDANCE SHEET 2: Parental Consent

Once infants have been identified (see Guidance Sheet 1: Eligibility), the clinical team should approach parents to discuss the trial. This should happen promptly after a Lumbar Puncture (LP) has become clinically indicated, to allow sufficient time for an informed decision.

Collect a Participant Pack from the Site Document Box. This contains a copy of the Parent Information Leaflet, the Consent Form, the Consent Checklist, the Parent Questionnaires and the First Lumbar Puncture / Lab Results Log.

Parent(s) should have been given a copy of the Parent Information Leaflet and given time to read this and discuss the study with the medical team. For families where there is a high index of suspicion (e.g. definite chorioamnionitis), consider mentioning the trial at the time of the initial septic screen.

Written informed consent must be obtained before an infant can take part in NeoCLEAR.

Who can take consent?

Consent to Lumbar Puncture (LP)

Procedural consent for the lumbar puncture should be taken by the clinical team in accordance with GMC Good Medical Practice guidelines and local standard procedures.

Consent to NeoCLEAR

In order to take **informed written consent for NeoCLEAR**, practitioners must have **GCP training** and **NeoCLEAR training**. The names of trained members of staff should be entered onto the site **Delegation Log**. This is kept in the Investigator Site File.

Ensure that parents are aware that participation is voluntary and that consent may be withdrawn at any time without explanation, without this affecting the family's quality of care. If they choose to withdraw, they will be asked if data collection can be completed. Allow sufficient time for the parents to ask any questions and consider their decision.

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Who may give consent?

Where possible, both parents should be involved in the consent process, however the birth **mother must** sign consent to the main study (first half of the consent form).

Written consent should be sought from the birth mother of the eligible infant. In cases where the mother is unable to provide written consent, fathers/partners may sign the consent form if they are married to the mother, or where their name is on the infant's birth certificate. If the father/partner has signed, the mother must countersign the consent form at the earliest opportunity/prior to discharge. *See page 4 for specific guidance on completing the consent form.*

Where the mother is under 16 years of age, she may be approached for consent by the medical team, if she is determined to be Fraser competent. She should be given adequate time to discuss the study with any family members or friends.

If a parent's capacity to give informed, voluntary consent is in doubt, their infant should not be recruited. Where there is disagreement amongst parents regarding the infant's participation, the infant should not be recruited.

GUIDANCE SHEET 2: Parental Consent

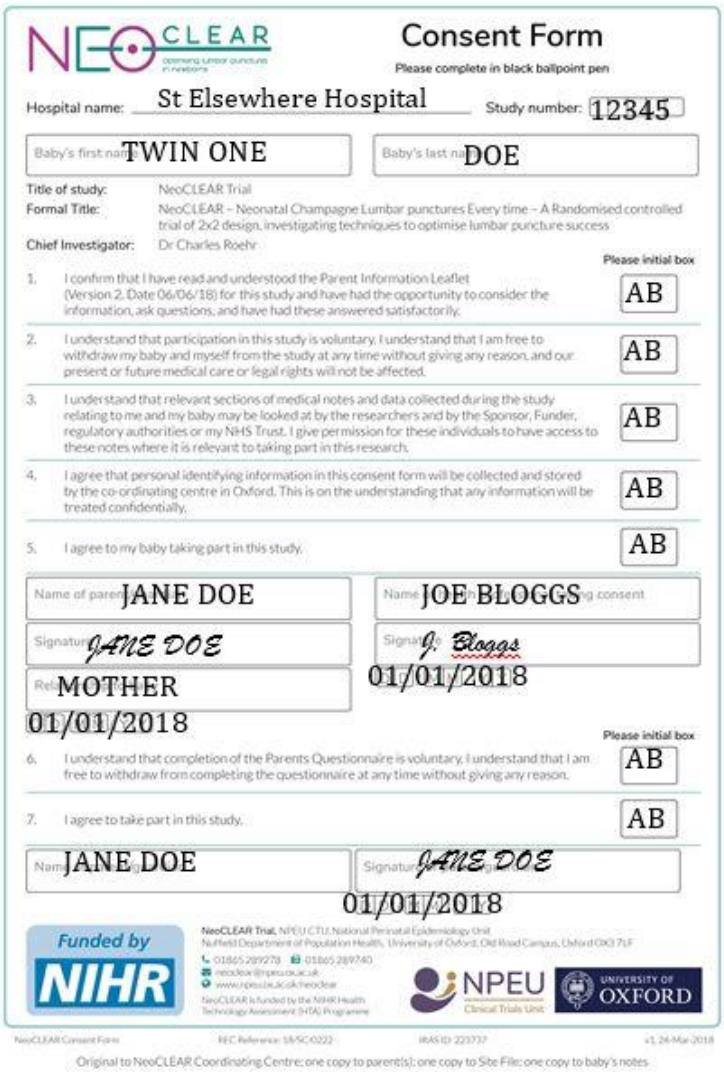
Key points to discuss with parents (as per GCP):

1. Consent is voluntary and will not impact any future treatment.
2. The purpose of the research is to determine which, if any, LP technique is best.
3. If they agree to participate, the infant has an equal chance of receiving any of the LP techniques. The same technique would be used for a second LP (if required). All have been studied before, but evidence is inconclusive and no single technique has yet been universally adopted.
4. The practitioner performing the LP will be trained in all techniques, all of which are safe and commonly used in different neonatal units.
5. Description of sitting versus lying, then early versus late stylet removal, with a level of detail tailored to the family. Then how the technique will therefore be one of four options: sitting with early stylet removal, sitting with late stylet removal, lying with early stylet removal, lying with late stylet removal.
6. Following consent, infants will be randomised using an NPEU online randomisation tool. (Parents will not usually be told to which technique their infant has been randomised)
7. Potential benefits of the trial:
    a. To future infants who require LP, if we can establish which technique is most likely to be successful.
    b. To reduce stress for future parents by finding the most successful LP technique. Parents will be asked to complete an optional questionnaire related to their anxiety levels before and after the procedure.
8. Potential risks of the trial: All trial techniques are standard care, so there are no known risks beyond those associated with LP. The risks of having an LP should have been covered in procedural consent.
9. Planned treatment course if they do not consent: Participation in the trial does not affect the clinical decision whether or not to perform an LP and will not affect the family's quality of care.
10. Parents can choose to withdraw from the trial at any point and do not have to give a reason.
11. As part of the study, data from medical records will be collected and kept securely as documented in the Parent Information Leaflet.
12. Data protection - it will not be possible to identify participants from any presentation, report or publication that may arise from this study.
13. Allow time for parent(s) to ask questions.
14. Explain the consent form – the first half of the consent form (clauses 1-5) MUST be signed by the birth mother, as they are giving consent for her and her baby to participate in the trial. Either or both parent(s) can consent to complete the Parent Questionnaire (clauses 6 & 7). The parent(s) consenting for this section must be the one(s) to complete both Parent Questionnaires.
15. Document parental consent to NeoCLEAR in the infant's medical notes.

GUIDANCE SHEET 2: Parental Consent

Completing the consent form

The consent form **must be signed and dated** by the parent(s) and the healthcare professional taking consent. The professional taking consent should read through the consent form with the parent(s) and the parent(s) should ***initial (not tick)*** each box **before signing and dating the form** (***do not complete in advance***). **Any clinician signing this form must be on the Site Delegation Log**. The dates for the parent and clinician signature must be the same. Parents must not be given a consent form to 'take away and sign'.



NEO CLEAR

Consent Form

Please complete in black ballpoint pen

Hospital name: St Elsewhere Hospital Study number: 12345

Baby's first name: TWIN ONE Baby's last name: DOE

Title of study: NeoCLEAR Trial

Formal Title: NeoCLEAR – Neonatal Champagne Lumbar punctures Every time – A Randomised controlled trial of 2x2 design, investigating techniques to optimise lumbar puncture success

Chief Investigator: Dr Charles Roehr

		Please initial box
1.	I confirm that I have read and understood the Parent Information Leaflet (Version 2, Date 06/06/18) for this study and have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.	AB
2.	I understand that participation in this study is voluntary. I understand that I am free to withdraw my baby and myself from the study at any time without giving any reason, and our present or future medical care or legal rights will not be affected.	AB
3.	I understand that relevant sections of medical notes and data collected during the study relating to me and my baby may be looked at by the researchers and by the Sponsor, Funder, regulatory authorities or my NHS Trust. I give permission for these individuals to have access to these notes where it is relevant to taking part in this research.	AB
4.	I agree that personal identifying information in this consent form will be collected and stored by the co-ordinating centre in Oxford. This is on the understanding that any information will be treated confidentially.	AB
5.	I agree to my baby taking part in this study.	AB

Name of parent: JANE DOE Name of person taking consent: JOE BLOGGS

Signature: JANE DOE Signature: J. Bloggs

Relationship: MOTHER 01/01/2018

01/01/2018

		Please initial box
6.	I understand that completion of the Parents Questionnaire is voluntary. I understand that I am free to withdraw from completing the questionnaire at any time without giving any reason.	AB
7.	I agree to take part in this study.	AB

Name: JANE DOE Signature: JANE DOE

01/01/2018

Funded by NIHR

NeoCLEAR Trial, NPEU CTU, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Old Road Campus, Oxford OX3 7LF

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NeoCLEAR is funded by the NIHR Health Technology Assessment (HTA) Programme

NPEU Clinical Trials Unit

UNIVERSITY OF OXFORD

NeoCLEAR Consent Form REC Reference: 18/SC/0222 IRAS ID: 223737 v1, 24-Mar-2018

Original to NeoCLEAR Coordinating Centre; one copy to parent(s); one copy to Site File; one copy to baby's notes

Separate consent forms will be required for twins, triplets, etc. Please make this clear on the consent form e.g. FIRST NAME (TWIN 1) LAST NAME.

Please complete the consent form in block capitals. Ensure all boxes are completed and that writing is clearly legible.

GUIDANCE SHEET 2

GUIDANCE SHEET 2: Parental Consent

Study ID

Once a participant has been randomised via the Consent and Randomisation Website (see Guidance Sheet 3), the study ID for the participant should be completed on the consent form (and on any subsequent documents).

Documentation

- There are four copies of the Consent Form. Once complete, a clear scanned copy should be emailed to orh-tr.NeoCLEAR@nhs.net from an nhs.net email address.

  Please only use nhs.net email addresses to ensure patient confidentiality.

  If this is not possible, please post the top copy of the consent form to NPEU using the freepost envelopes provided in the Site Document Box at the earliest opportunity. (Please affix your site return address label to the back of the envelope.)

  Give one copy to the parent(s) and file one copy in the medical notes. The remaining copy(s) should be kept in the Participant Pack and filed in the Active Participant File.

- Complete the **Enrolment Log** in the Investigator Site File.

- Give the parent(s) a Parent Questionnaire from the Participant Pack to complete before the first LP and within two hours of consent where possible. This questionnaire must be given to the same parent(s) who signed clauses 6 & 7 of the consent form. **Please add the Study ID and tick the First Questionnaire box** on the front of the Parent Questionnaire. Ensure the name of the parent completing the questionnaire is completed (not the infant's name).

  It should be made clear to the parent(s) that the information they provide in the Parent Questionnaire is confidential.