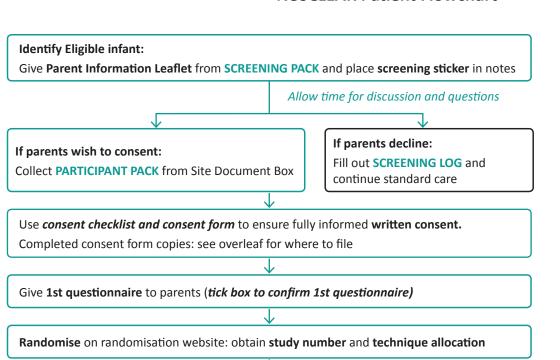
NeoCLEAR Patient Flowchart



1 x Parent Information



Place 1 copy in patient notes and 1 in participant pack

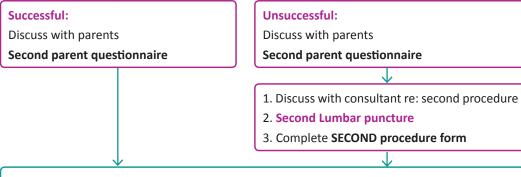
Print allocation from randomisation x 2 copies

1. Collect First Parent Questionnaire; file in Participant Pack.

2. Lumbar puncture

3. Complete information on FIRST procedure form, keep procedure form in participant pack

ENTER STUDY ID onto participant pack, questionnaires, consent form and procedure form.



Monitor for SAEs (See Guidance sheet 6: SAEs)

Ensure all pages of patient documentation have study ID entered

RN/delegate to complete data on electronic electronic Case Report Form

AT THE END OF THE STUDY:

Each patient must have a participant pack with:

- Signed consent form
- Printed allocation from randomisation
- 2 parent questionnaires
- FIRST procedure form

ADDITIONALLY, some patients will have:

- Second procedure form
- SAE form

ALL must be labelled with study ID and kept securely in the PARTICIPANT PACK.

PARTICIPANT PACK

1 x Screening Sticker

SCREENING PACK

Leaflet

- 1 x consent form (with 3 carbon copies)
- 1 x consent checklist
- 2 x parent questionnaires
- 1 x First Procedure form

Forms to be completed online:

- Trial Entry
- Randomisation
- 2 parent questionnaires
- FIRST procedure
- Outcome form

Optional:

- SECOND procedure
- SAE form
- Withdrawal form