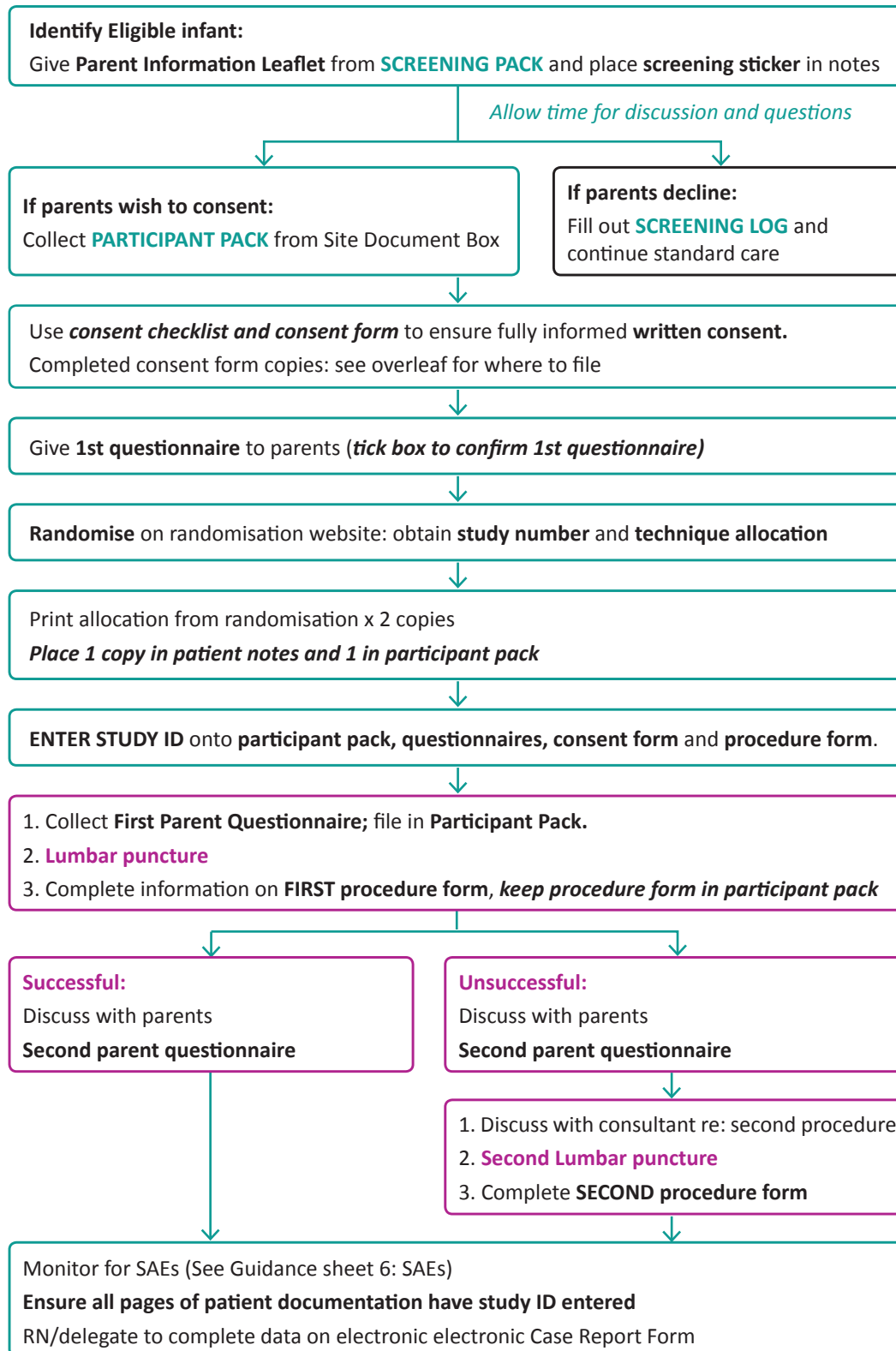


NeoCLEAR Patient Flowchart



SCREENING PACK

1 x Parent Information Leaflet
1 x Screening Sticker

PARTICIPANT PACK

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

Forms to be completed online:

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

Optional:

- SECOND procedure
- SAE form
- Withdrawal form