

HELIX Number

Date of consent
Time of consent
Person taking consent (Consultant/PG student)
Trainee/PI
Research nurse present (Y/N)
Consent outcome (Given/Refused)
Outcome of baby (survived/died)
VIDEO SCORING
EMPATHY
1. Dr showed empathy and respect to the parents
2. Dr used a regional language understood by parents and avoided medical jargon
INFORMATION
3. Dr explain why the baby has been selected for the study
4. Dr explained the purpose of the study
5. Dr explained all the study procedures - details of Cooling therapy and duration
6. Dr explained all the study procedures - infection test from blood and umbilical cord
7. Dr explained all the study procedures - MRI scan within 2 weeks
8. Dr explained all the study procedures - Follow up at 18 months
9. Dr explained randomisation (50:50 chance of cooling or usual care decided by a computer)
10. Dr explained the potential benefits of the study
11. Dr explained the potential risks of the study
12. Dr explained how the research costs will be covered and explain any remuneration
13. Dr explained that participation was voluntary, non-participation would not affect the care; and avoid use of any coercion
14. Dr explained parents could withdraw from the study any time without giving any reason
15. Dr explained how confidentiality of the data (names etc) will be maintained
16. Dr provided information about the ethics and regulatory approvals of the study
AUTONOMY
17. Dr encouraged the parents to ask questions and then respond adequately
18. Parents asked appropriate questions (if so, please please record the questions asked by parents)