

Consent Form for Parent/Guardian of Newborn Infant Cooling in Mild Encephalopathy Trial (COMET)

For Hospitals That Offer Cooling Treatment on Site
(Neonatal Unit Intensive Care Units)

Chief Investigator: Professor Sudhin Thayyil

Please complete form using BLOCK CAPITALS

Name of recruiting Hospital:	
Name of Principle Investigator (PI):	
Subject ID:	
Baby's first name and last name:	
Baby's date of birth (dd/mm/yyyy):	
Name of delegated study personnel explaining study to parent:	

Mandatory section (please initial all boxes) for participating in trial:

Initials here

1	I confirm that I have read and understand the Parent Information Sheet Version [], Date [/ /]. for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2	I understand that my child's participation is voluntary, and I am free to withdraw at any time, without giving any reason and without any legal rights nor treatment / healthcare being affected.	
3	I understand that relevant sections of medical records and data collected during the study relating to me or my baby may be looked at by the research team, sponsor, regulatory authorities and this NHS Trust. I give permission for these individuals to have access to these records where it is relevant to taking part in this research.	
4	I have been informed about what the data collected will be used for, to whom it may be disclosed and for how long it will be stored.	
5	I agree that you may use my baby's data (including imaging data and aEEG) obtained as part of standard clinical care for research.	
6	I understand that as part of this study my baby will have a detailed check-up to see how they are learning and growing when they are between 22 and 26 months old. This will also include filling out a questionnaire. To arrange this follow-up assessment, authorised members of the COMET research team at Imperial College London may contact me using the details provided.	
7	I agree for information on my baby's future health status to be collected and analysed in strict confidence by responsible researchers conducting this study. This includes information held in electronic medical records and other relevant registers including the National Neonatal Research Database at Imperial College London. I understand that identifiable information including my baby's NHS number will be used to trace future data.	

8	I understand that data collected are a gift donated to Imperial College and that I will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication or treatment.	
9	I agree that my child's pseudonymised (personal information replaced with codes) data from the COMET study can be linked to other research databases and shared with other researchers.	
10	I agree that you may contact my local hospital where my baby might have continued care and request relevant clinical information from them.	
11	I agree that you may contact my GP to inform them about my baby's participation in this study and request clinical information from them.	
12	I agree to my baby taking part in this study.	

Optional section (initial relevant boxes if applicable):

1	I consent for my baby's neurological assessment to be video recorded and to be shared with neurology experts at Imperial College London to help improve quality assurance and for the training of clinicians and nurses.	
2	I agree to be contacted with questionnaires about my baby's NHS and social care use at 6, 12, 18, and 24 months. I understand that completing them is voluntary and they can be done online or by post	
3	I consent for information collected about my baby to be used to support other research or in the development of a new test, medication, medical device or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom. Imperial College London will keep this information secure.	
4	I consent to my child being contacted about potentially taking part in other research studies for the next 10 years.	

Name of parent / legal guardian

Signature

Date

Name of person obtaining consent
(must be listed on the site delegation log)

Signature

Date

Please obtain **Mother's countersignature** below as soon as possible if other parent has provided original consent:

Mother's name

Signature

Date

1 copy each for the participant, site file, and hospital notes. Consent forms must be printed, signed, and stored double-sided.

COMET Trial – Contact Details for Follow-up (24-Month Assessment)

(To be detached and stored separately from the consent form)

Study Identifiers (to be completed by research staff)

Randomisation Number (3-digit):						
Subject ID (6-digit):						

Parent / Guardian Contact Details

As discussed in the consent form, your child will be invited for a developmental assessment at around 24 months of age. To help us arrange this follow-up, please provide the best telephone number to contact you.

Best contact mobile number:											
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Use of Your Contact Details

- This telephone number will be used only to arrange your child's follow-up assessment.
- It will be stored securely and separately from your child's study data.
- It will be accessed only by authorised members of the research team.
- It will not be used for any other purpose.
- It will be deleted at the end of the study, in line with UK data protection regulations.

Providing a contact number will help us arrange follow-up. If you choose not to provide this, we may not be able to contact you to arrange your child's assessment.

Research Staff Record (to be completed by site team)

I confirm that the above contact details were provided by the parent/guardian in the context of informed consent for the COMET trial.

Name of person obtaining consent
(must be listed on the site delegation log)

Signature

Date