Parent/Guardian Telephone Consent Form

Please complete in black ballpoint pen

Pre-requisites

- Telephone consent should only be obtained if written parental consent within 6h of birth is not possible.
- Telephone consent must be obtained before randomization.
- Clinician must inform parent(s) about the health status of the baby, prior to discussing research.
- In addition to the clinician taking research consent, a healthcare professional must be present to witness the telephone conversation, using a speakerphone option. Other relatives or friends can be present in the room too, according to the parent's permission.
- Interpreters should be used if the parents are unable to speak English.
- Only GCP trained neonatal doctors who have been signed off in the delegation log should obtain consent. All aspects of the study mentioned in the parental information sheet should be explained to the parents, prior to obtaining the consent.
- Specific consent sessions of the consent form below (version x, date) should be explained to the parents, and the relevant boxes should be initialled by the person taking consent.

NHS Hospital:…….

Name of Principal Investigator: ……..……

Child's Name: ….……..……..….

This study has been explained to me by: *(delete as appropriate)*
Prof/ Dr/ Mr/ Mrs/ Ms ……..…

Please listen and confirm whether you agree or not agree to give consent for the following points below. If you require help with listening or translation of this document, please ask a member of the clinical/research team to support you.

	Please initial box
1. I confirm that I have read and understand the participant information leaflet dated ..... version ..... for Cooling in mild encephalopathy (COMET) trial and have had the opportunity to ask questions which have been answered fully.	

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2. I understand that my child's participation is voluntary, and I or my child are free to withdraw at any time, without giving any reason and without any legal rights nor treatment / healthcare being affected.	
3. I understand that sections of any of my child's medical notes may be looked at by responsible individuals from Imperial College London, from NHS Trust or from regulatory authorities where it is relevant to my child taking part in this research.	
4. I agree that you may use my baby's data (including imaging data and aEEG) obtained as part of standard clinical care for research.	
5. I agree for the video recording of my baby's neurological assessment to be shared with neurology experts at Imperial College London to help improve quality assurance and training of clinicians and nurses.	
6. As part of the study follow-up, I understand that my baby will have a detailed neurodevelopmental assessment between 22 and 26 months of age, including the completion of a questionnaire.	
7. I give / do not give (delete as applicable) consent for information collected about my child to be used to support other research or in the development of a new test, medication, medical device or treatment (delete as applicable) by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure).	
8. 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.	
9. I agree for my baby's information and the blood sample that has been taken for this study to be stored on a long-term basis at Imperial College London for use in future ethically approved research. The data (including identifiable data) and any remaining samples may be stored securely at Imperial College London and the local hospital for 10 years following the completion of the study.	
10. I give / do not give (delete as applicable) consent for blood samples to be used to support other research by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure).	
11. I understand that blood samples and / or data collected are a gift donated to Imperial College and that I will not personally benefit financially	

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if this research leads to an invention and/or the successful development of a new test, medication or treatment.	
12. I agree that my child´s pseudonymised data that were generated or collected as part of the COMET study can be linked to other clinical research databases and that these data can be shared with other researchers.	
13. I give / do not give (delete as applicable) consent to my child being contacted about potentially taking part in other research studies for the next 10 years.	
14. 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.	
15. I agree that you may contact my local hospital where my baby might have continued care and request relevant clinical information from them.	
16. I agree to my child taking part in the Cooling in Mild Encephalopathy (COMET) trial.	

Please ensure all sections are signed and dated below:

_____	_____	_____
Name of parent / legal guardian	Signature	Date
_____	_____	_____
Name of person taking consent (if different from Principal Investigator)	Signature	Date
_____	_____	_____
Principal Investigator	Signature	Date

1 copy for participant; 1 copy for Principal Investigator 1 copy for hospital notes

To ensure confidence in the process and minimise risk of loss, all consent forms must be printed, presented and stored in double sided format.