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Telephone Consent Form for Parent/Guardian

Cooling in Mild Encephalopathy (COMET) trial

Please complete in black ballpoint pen

Pre-Consent Checklist:

1. **Eligibility for Telephone Consent**: If written parental consent within 6h of birth is not possible. Telephone consent must be obtained before randomization.
2. **Personnel Requirements**: Consent must be obtained from a GCP-trained clinician listed on the delegation log. 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.
3. **Interpreter Services**: If the parents are unable to speak English, NHS-provided interpreter services must be utlizied.
4. **Information Delivery**: Clinician must inform parent(s) about the health status of the baby, prior to discussing research. The Parent Information Sheet (PIS) must be provided to the parent/guardian prior to the call, either electronically or by other means. All aspects of the study mentioned in the parental information sheet should be explained to the parents, prior to obtaining the consent. Each specific consent sections below (version x, date) should be explained to the parents, and the relevant boxes should be initialled by the person taking consent.

Please complete form using BLOCK CAPITALS

Hospital Name:	
Name of Principle Investigator (PI):	
Subject ID:	
Baby's date of birth (dd/mm/yyyy):	
Date and Time of Consent Call:	

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Verbal Consent Statement

The clinician taking consent should confirm and document verbal responses for each statement

(No.) Statement	Response (Yes/No)
(1). I confirm that I have received and understood the participant information leaflet dated ..... version ..... for Cooling in mild encephalopathy (COMET) trial and had the opportunity to ask questions which have been answered fully.	
(2). I understand that participation is voluntary, and I can withdraw my baby 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 baby'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 baby 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). 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 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 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.	
(9). 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.	
(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 to my child taking part in the Cooling in Mild Encephalopathy (COMET) trial.	

Optional section (initial relevant boxes if applicable):

(1) 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).	
(2) 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.	

Declarations

1. Parent/Guardian Verbal Consent Statement: I confirm that I have provided verbal consent for my child's participation in the COMET trial.

_____	_____	_____
Name of Parent / Legal Guardian	Relationship to Baby	Date

2. Witness Declaration (Healthcare Professional): I confirm that I was physically present during the telephone consent process and witnessed the parent/guardian providing informed verbal consent for participation.

_____	_____	_____
Name of Witness/Job Role	Signature	Date

3. Person Taking Consent Declaration: I confirm that I have explained the study, answered questions, and obtained informed verbal consent.

_____	_____	_____
Name of person taking consent (must be listed on the site delegation log)	Signature	Date

Full written consent must be obtained at the earliest opportunity once the parent or legal guardian is physically present in the neonatal unit.

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.