



COLLABORATE Sub-Study - Consent Form

COLLABORATE: A large study across the UK using real-world data to test the effects and safety of common feeding methods in reducing serious health issues in very premature babies.

Site Number/Name:	
Name of Principal Investigator:	
Participant Study ID Number:	
Child Name:	

Please Initial Box

1. I confirm that I have read and understood the Parent/Carer information sheet dated version for the COLLABORATE sub-study and have had the opportunity to ask questions which have been answered fully.	
2. I understand that my baby's participation is voluntary, and I or my baby 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 my baby's medical notes may be looked at by responsible individuals from the Sponsor (Imperial College London), the NHS Trust or from regulatory authorities where it is relevant to my baby taking part in this research.	
4. I understand that samples and data collected are a gift donated to Imperial College and that neither I nor my baby will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication or treatment.	
5. I understand that if I withdraw my baby from the study, any data already collected can still be used.	
6. I agree to my child taking part in the COLLABORATE sub-study.	

OPTIONAL CLAUSES

Please Initial Box

7. I give 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 (which Imperial College has ensured will keep this information secure).	
8. I give consent to sharing contact details for myself to be informed of regular newsletter updates and the results of the COLLABORATE sub-study once available.	
9. I give consent to sharing contact details for myself or my baby to be contacted about potentially taking part in other research studies. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	

Please complete either the stool or imaging clauses or both

IMAGING CLAUSES

Please Initial Box

10. I agree to my baby undergoing an MRI scan as part of the COLLABORTAE imaging sub-study.	
11. I give permission for my baby's GP to be informed of participation in this imaging study.	

STOOL SAMPLES CLAUSES

Please Initial Box

12. I agree to the collection and storage of stool (faeces) from my baby for studies of the effect of milk type on gut bacteria, health and brain development, including analysis of the bacterial DNA.	
13. I give consent for samples collected 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 (which Imperial College has ensured will keep this information secure).	
14. I understand that if I withdraw my baby from the study, any stool samples already collected can still be used, unless I request for them to be destroyed.	

PLEASE TURN OVERLEAF FOR SIGNATURES

Name of Parent / Legal
Guardian

Signature

Date

Name of person taking consent

Signature

Date

Original copies should be filed in the ISF plus 1 copy for participant and 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.