

THE COLLABORATE STUDY

Parent Information Leaflet Part 2

A UK study to assess the effect of common feed types in reducing serious health issues in preterm babies born less than 29 weeks gestational age

Who is organising and funding the COLLABORATE study?

The study is being organised and run by researchers at Imperial College London, the Universities of Edinburgh, Newcastle, Oxford, Cambridge, and Nottingham, Health Data Research UK, Bliss (the national charity for babies born preterm or sick) and the Adult Preemie Advocacy Network. COLLABORATE is funded by the National Institute for Health Research.

Who is providing oversight of the COLLABORATE study?

An independent group of experts and people with lived experience will provide oversight. A Data Monitoring Committee will review results as they accumulate so that the study can be stopped as soon as reliable answers are available. A Trial Steering Committee provides advice and guidance and helps troubleshoot any issues that may arise.

What will happen to the results of the COLLABORATE study?

The results will be presented at national and international conferences and published in medical journals to inform healthcare practitioners worldwide. Neither your baby nor you will be identifiable in any publication. Once the results are published, we will also send these to you unless you ask us not to.

Who has approved the COLLABORATE study?

All research in the NHS must be approved by an independent group, called a Research Ethics Committee. COLLABORATE has been approved by **London - Bloomsbury** Research Ethics Committee.

Who can I contact for independent information?

If you have any general questions about your baby taking part in a study like COLLABORATE, you can contact your hospital's Patient Advice Liaison Service.

What if something goes wrong?

It is extremely unlikely anything can go wrong as a result of participating in COLLABORATE because all feed options are already in routine use throughout the UK. However, Imperial College London holds insurance policies which apply to this study. This means that if your baby experiences harm or injury because of the research, you will be eligible to claim compensation without having to prove that Imperial College London is at fault. This does not affect your legal rights to seek compensation. If your baby is harmed due to someone's negligence you may have grounds for a legal action.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you and your baby have been treated during this study you should immediately inform the named lead medical investigator using the contact details provided at the bottom of Part 1. The normal National Health Service complaints mechanisms are also available to you. If for any reason you are not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team at rgit@imperial.ac.uk.

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PRIVACY NOTICE

A Privacy Notice is a legal requirement

How will we use information about you and your baby

Imperial College London is the sponsor for this study and will act as the data controller for this study. Being a Data Controller means that we are responsible for looking after your and your baby's information and using it appropriately plus are responsible for explaining this to you. Imperial College London will keep your and your baby's personal data for 10 years after the study has finished. The study data will then be fully anonymised and securely archived or destroyed.

The study is expected to finish in May 2030.

We will need to use information from your baby's medical records for this research project. This information will include your name, contact details and your baby's NHS/CHI/H&C number and date of birth. People within the college and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that the research is being done properly and the information held (such as contact details) is accurate. People who do not need to know who you are will not be able to see your name or contact details. You and your baby's data will have a code number instead. We will keep all information about you and your baby safe and secure.

Imperial College London is the sponsor of this research, and is responsible for looking after your and your baby's information. We will keep all information about you and your baby safe and secure by:

- Data management plans have been created and reviewed in line with Imperial's Information Governance Policy Framework. This covers the collection, movement, processing and storage of the data.
- Data to be stored in a dedicated secure environment which underpins security measures.
- Data will be stored in ISO 27001 certified environment.
- Robust pseudonymisation (for example, where real names are swapped out for numbered codes) has been implemented to prevent identification.
- Access controls have been implemented to ensure only key personnel can access the data.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your baby took part in the study.

As a university we use personally-identifiable information to conduct research to improve health care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use you and your baby's data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

- Imperial College London - “performance of a task carried out in the public interest”; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](#).
- Where special category personal information is involved (most commonly health data, biometric data i.e. finger prints or facial recognition and genetic data, racial and ethnic data etc.), Imperial College London relies on “scientific or historical research purposes or statistical purposes.

International Transfers

We may share data about your baby outside the UK for research related purposes to:

- Where necessary provide access to a data processor / service provider who will utilise your baby’s personal data as instructed by us.

If this happens, we will only share the data that is needed. We will also make sure your baby can’t be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if your baby has a rare illness, it may still be possible to identify your baby. If your baby’s data is shared outside the UK, we will make sure their data is protected. Anyone who accesses your baby’s data outside the UK must do what we tell them so that your baby’s data has a similar level of protection as it does under UK law. We will make sure your baby’s data is safe outside the UK by doing the following:

- We use specific contracts which stipulates that personal data must maintain the same level of protection when outside the UK as it has within the UK. For further details visit the Information Commissioner’s Office (ICO) website - www.ico.org.uk .
- We do not allow those who access your baby’s data outside the UK to use it for anything other than what our written contract with them says.
- We need other organisations to have appropriate security measures to protect your baby’s data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your baby’s data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website - [Personal data breaches: a guide | ICO](#).

Sharing your information with others

We will only share your and your baby’s personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your and your baby’s data as set out above. This data may be shared with the following third parties:

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc).
- Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

- Research Collaborators / Partners in the study
 - Queen's University Belfast, Newcastle University, The University of Edinburgh, University of Oxford, University of Nottingham and University of Cambridge, our research collaborators assisting with analysing the results.
 - Bliss, Adult Premie Advocacy Network and Health Data Research UK, our charity partners.

Potential Use of Study Data and Samples for Future Research

When you agree to take part in a research study, the information and samples collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London or to other organisations or universities involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the [UK Policy Framework for Health and Social Care Research](#).

This information will not identify you and will not be combined with other information in a way that could identify you, be used against you or be used to make decisions about you.

Commercialisation

Data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your or your baby's name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (where all identifying information is removed) may also be created using your baby's data (in a way which does not identify your baby individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your baby's data will not be shared with a commercial organisation for marketing purposes.

What are your choices about how your information is used?

You may withdraw your baby from participation in COLLABORATE at any time, without giving a reason. We will keep information that we already have because this is needed for the research to be reliable.

You have the right to ask us to access, remove, change or delete data we hold about you or your baby for the purposes of the study. You can also object to our processing of you or your baby's data. We might not always be able to do this if it means we cannot use the data to do the research. If so, we will tell you why we cannot do this.

If you choose for your baby to stop taking part in the study, we would like to continue collecting information about their health from the National Neonatal Research Database. If you do not want this to happen, tell us and we will stop.

If you agree for your baby to take part in this study, you will have the option to take part in future research using their data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your baby's information at www.hra.nhs.uk/information-about-patients/, the leaflet available from www.hra.nhs.uk/patientdataandresearch, or by asking one of the research team.

Complaint

If you wish to raise a complaint on how we have handled your personal data, please contact the research team first by sending an email to collaborate@imperial.ac.uk.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) - via www.ico.org.uk. The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

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