



Parent Information Leaflet – Sub-Study

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.

This neonatal unit is part of a UK-wide study to find the best way to feed very premature babies (born before 29 weeks of pregnancy). Your baby is already part of this study, it's called COLLABORATE.

You are being invited to consider including your child in the **COLLABORATE MRI and stool sampling sub-study**. Before you decide it is important for you to understand why the research is being done and what it will involve for your child. Please take time to read the following information carefully and discuss it with others if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you would wish your baby to take part. Thank you for taking the time to consider your baby taking part in our imaging sub-study.

What are we trying to find out?

We want to discover how and why premature birth affects the developing brain so that we can develop new treatments to help children who are born early.

In the UK, premature birth affects 6-7% of babies. About half of premature babies develop problems as they grow up, which can include diagnoses such as cerebral palsy or problems with learning, behaviour or educational difficulties. There are no treatments to prevent these problems, and we do not know how to provide the best support for those children who develop them. We want to find new ways of helping children born too soon. As part of the COLLABORATE study your baby has been randomised to either receive pasteurised human donor milk or preterm formula if there have been times when mother's own milk has been in short supply. That was to find out whether the type of milk a baby receives if mother's own milk is in short supply increases or decreases the likelihood of surviving without needing an operation for necrotising enterocolitis. We do not know whether these two ways of supplementing mother's own milk have different impacts on the developing brain. In this MRI study, we will find out whether there are

COLLABORATE Imaging Sub-Study Parent / Carer Information Sheet

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differences in brain development depending on whether a baby has been fed with pasteurised human donor milk or preterm formula milk at times when their mother's own milk was in short supply. Once we know this, scientists will be better positioned to design treatments that could help.

Scientists think that the type of milk a baby receives during neonatal intensive care changes the type of bacteria ('bugs') in the gut, and this might affect brain development. Therefore, we would like to take poo samples, which tell us about the bacteria in your baby's gut. In future, we will analyse these to whether type of milk supplements changes the bugs that live in the gut, and if so, whether this change is associated with health and brain development.

We hope that 120 babies who are born preterm will take part in this sub-study.

Why have I been invited to take part?

Your baby is invited to participate in this research study because your baby has been born early, at less than 29 weeks, and is participating in the COLLABORATE study.

Does my baby have to take part?

No, it is up to you to decide whether or not your baby takes part. Taking part in this sub-study does not affect your baby's participation in the COLLABORATE study. We know this is a difficult time so take as long as you need, you won't be rushed into anything. If you do decide your baby will take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide you would like your baby to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that your baby receives, or your legal rights.

What will happen if my baby takes part?

There are 2 aspects to this sub-study, MRI scans and stool samples. Your baby can take part in either or both aspects.

MRI scan

Sometime near your baby's due date, your baby will be invited for an MRI scan. Magnetic resonance imaging (MRI) of the brain provides very detailed pictures that cannot be obtained in any other way (Figure 1). It is safe and does not involve radiation.

MRI tells us about brain structure and how the nerve pathways connect. By using MRI, we can study how connections are changed by premature birth.

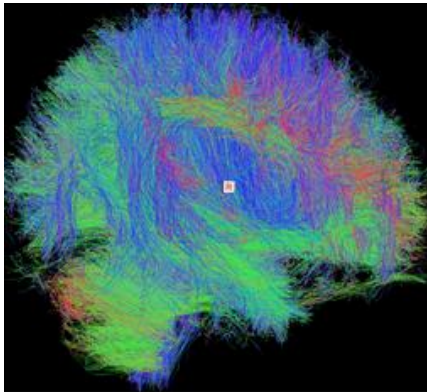


Figure 1: Newborn brain MRI showing connections.



Figure 2: The MRI scanner

The scan will take place at the Brain Research Imaging Centre in the Royal Infirmary of Edinburgh. When you arrive you and your baby will be greeted by a research team member who will take you to the MRI suite.

Before the scan, one of the research team will perform a routine check and examination of your baby. We will confirm that your baby is well with no signs of coughs or colds, and that he/she is fit for MRI scanning. We ask that your baby does not wear any jewellery, religious artefacts or clothing with metal ‘poppers’ because the presence of metallic objects can affect the quality of the images.

The MRI scanner is a cylinder-shaped tube surrounded by a circular magnet (Figure 2). Your child will be swaddled in a blanket and placed on the examination table whilst asleep, usually after being settled with a feed. We ensure your baby is secure by using a special wrap, which helps settle them. The table slides on runners into the centre of the circular magnet. Next to the scanner is the control room where the radiographer taking the pictures sits. This has clear views into the scanner. You can be with your baby until the scan starts and immediately when it finishes. While your baby is in the scanner you can get a tea or coffee (either in the imaging centre coffee room or nearby in the hospital), or go into the scanner room with your baby assuming that you are happy to undergo MRI safety screening required for all people who go in the scanner room, and are happy to wear ear phones to dampen down the noise of the scanner.

The scan will last about 60 minutes. Your baby’s oxygen levels and heart rate will be monitored during the scan. A researcher who is clinically qualified to care for babies (doctor, nurse or midwife) will be present in the control room observing your baby. We will also monitor your baby’s oxygen and heart rate after the scan has finished, until they wake up and have a feed. Some babies wake and feed soon after the scan but others may take longer, depending on their feeding habits, but in our experience babies tend to have woken within an hour. The total time taken for the MRI scan appointment may be as much as 2 hours or even a little longer to include the 60 minutes of the scan itself plus the up to 60 minutes your baby may take to wake up and feed.

We try to make sure that babies go to sleep naturally, as they need to be as still as possible for the scan to work. We achieve this by letting your baby have a feed and swaddling them. If your baby likes a pacifier we can also use this during the scan. We have found that these simple methods usually enable the baby to sleep through the whole scan.

We will pay your travel expenses to attend the MRI scan and you will receive a £20 shopping voucher. After the scan, we will send you a high-quality print of your baby's brain to keep.

Stool Samples

We want to collect samples of your baby's stool because we are planning studies to understand whether the type of milk a baby receives during neonatal intensive care alters the mixture of bacteria in his/her gut, and if so, whether this affects brain development. We will take a sample at the point of joining the study and each week until your baby reaches 34 weeks. A member of the research team will take the sample, we do this by keeping a dirty nappy.

If you have also consented for your baby to have an MRI scan, we will take an additional sample they come in for their MRI brain scan.

Is there anything I need to do or avoid?

There are no special precautions or requirements for you or your baby.

Why take part?

There are no direct benefits to your baby taking part in this sub-study alongside the COLLABORATE study, however by participating, you will help improve the care of very premature babies in the future.

PART 2 – Frequently Asked Questions

What are the possible disadvantages of taking part?

There are no known risks from MRI when it is used according to guidelines in place in the NHS and the University of Edinburgh. It does not involve ionising radiation. The MRI scanner makes a loud knocking noise during the scan, so ear plugs and muffs are used to prevent discomfort due to noise, and to encourage your baby to sleep. As MRI scanners use a strong magnet, care must be taken to keep metallic objects away.

A consultant radiologist will review your baby's scan. The scan is unlikely to show any problems that are known to affect your baby. Rarely, there may be a finding that requires further assessment or treatment. If this is the case, we will tell you and your GP and refer your baby to appropriate NHS services.

What if there are any problems?

Imperial College London holds insurance policies which apply to this study. If your baby experiences harm or injury as a result of taking part in this study, you and your baby 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, then 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 the course of this study then you should immediately inform the doctor at your hospital using the contact details below. 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.

What will happen if I don't want to carry on with the sub-study?

You are free to change your mind at any point. Your baby's medical care will not be affected if you withdraw from the sub-study. If you decide you do not want to attend the MRI appointment, we ask that you contact one of our team on 0131 242 1665 or 07443 274839 so that we can re-assign the appointment to another baby.

If you withdraw from the study, we will keep the information about your baby and samples that we have already collected. If you do not want us to keep your baby's samples, please let the team know and these will be destroyed.

Will my baby's details and information be confidential?

Yes. All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your baby's privacy at every stage. All of your baby's personal details will be kept in a pseudonymised format (this means a code number will be used instead of their name and only their care team can link the code with their details) and confidential. Any results from the study will not allow your baby to be identified in any way.

What happens when the study is finished?

At the end of the project, pseudonymised data will be archived in safe, long-term storage within the University of Edinburgh. Researchers leading ethically approved projects will be able to request access to the anonymised data and a data sharing agreement between organisations will be used to ensure your information is used responsibly. Your baby will not be identifiable from any published results.

Any leftover samples will be stored by the research team at the University of Edinburgh for up to 2 years after the study has finished, for use in another ethically approved project. We need to keep your personal data for 10 years after the end of the study. It will then be destroyed.

What will happen to my samples?

The samples we collect from your baby will be taken to our laboratory in the University of Edinburgh, which is human tissue authority regulated, for future analysis. All activities (storage, use and disposal) concerning the samples will be carried out in accordance with the Human Tissue Act 2004. Samples will be stored beyond the end of the COLLABORATE project for use in other projects in which ethics approval will be sought. If the research team distributes these samples, to other individuals who have an interest in preterm babies, they will be anonymised and no names or medical record numbers will be shared.

This future work will involve DNA analysis of the bacteria in stool samples, as well as other types of scientific analysis for the samples you provide. We will not perform any analysis of your baby's DNA. Your baby's samples will be given a unique identification number and stored without their name. Only the team at your hospital will have a list to know which sample is linked to which participant and this list will be kept confidential in a secure location. If you consent, the samples provided may also be used in other ethically approved future research. Your baby will not be able to be identified from this work.

The results of tests performed on stored samples or reports resulting from the analysis of the samples will not be given to you or your baby's doctor and they will not be put in their medical record. Because we are using a research laboratory and not a laboratory with certified procedures for reporting results, we cannot directly give you the results from this research. They will not identify your baby and will not affect their routine medical care.

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 babies information and using it appropriately plus are responsible for explaining this to you. Imperial College London will keep your 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, ethnicity, address, post code, telephone number, CHI number and e-mail address.
- Your child's name, ethnicity, address, post code, CHI number and date of birth.

Note that the CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index and is personal identifiable information. Your CHI number is being collected to allow us to accurately identify you and your child to collect information from your medical records.

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 safe and secure.

Imperial College London is the sponsor of this research, and is responsible for looking after your baby's information. We will keep all information about you 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 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 your 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 to provide access to a data processor / service provider who will utilise your 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 data is shared outside the UK, it will be with the following sorts of organisations:

- organisations who store your data

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your 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 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 data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your 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 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 data as set out above.

- 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 Preemie 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 and in other organisations which may be universities or organisations 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, used against you or used to make decisions about you.

Commercialisation

Sample or 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 sample or data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your 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 and/or only the sub-study 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 to take part in this sub-study, you will also have the option to allow the research team to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team. Agreeing to be contacted does not oblige you to participate in further studies.

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 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.

What will happen to the results of the sub-study?

This study will be written up as publications in scientific journals and presented at scientific meetings. You will not be identifiable from any published results.

Results of the study will be made available to you. A parent advisory group will advise on the best ways to do this and will work with an artist to develop ways of communicating the results. We will share the results through newsletters, e-mail, the study website <https://www.imperial.ac.uk/neonatal-data-analysis-unit/collaborate/> and information days or events.

Who is organising and funding the research?

This sub-study has been organised by the University of Edinburgh and NHS Lothian. It is part of the COLLABORATE study sponsored by Imperial College London.

The study is funded by the National Institute for Health Research (Efficacy and Mechanism Evaluation programme). The sponsors of this study will pay your hospital the costs associated for including your baby in this sub-study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by **REC NAME** Research Ethics Committee.

Who can I contact for independent research information?

If you have any questions about being in a research study, you can contact the Trust's Patient Advice Liaison Service (PALS). They will give you advice about who you can talk to for independent advice.

Questions?

If you have any questions or concerns, please speak with a member of our team. We are happy to help.

Local Contacts

Principal Investigator: <inset name>

Local research nurse: <inset name>

<Insert contact details>

<Insert contact details>

<Insert PALS Name>: <Insert contact details>

The COLLABORATE Team

Imperial Clinical Trials Unit, Imperial College London

1st Floor Stadium House (Entrance A), 68 Wood Lane, London, W12 7RH

Tel: XXXX **Email:** collaborate@imperial.ac.uk

Website: <https://www.imperial.ac.uk/neonatal-data-analysis-unit/collaborate/>

