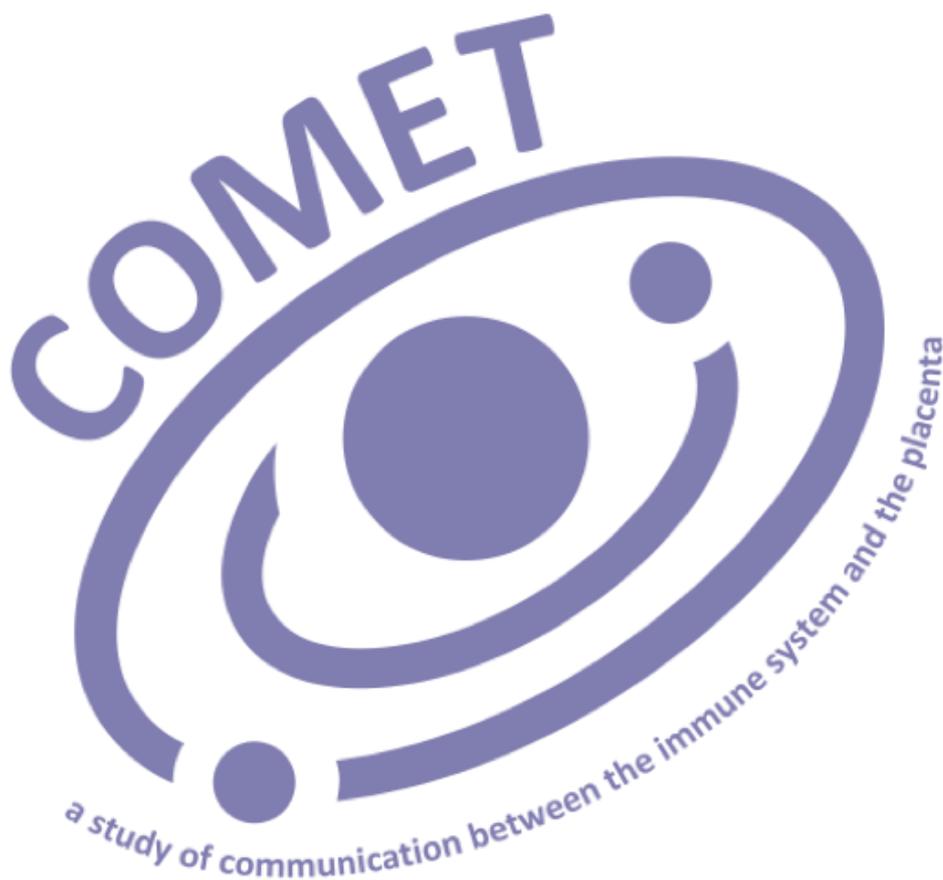


Information sheet for potential research participants having an elective caesarean section



Invitation to take part in a research study

When you attend your next appointment in the hospital, you may be invited to take part in a research study: **COMET- A study of communication between the immune system and the placenta.**

Before you decide to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Please ask us if there is anything that is not clear, or if you would like more information.

It is entirely your choice whether to take part in this research study. If you decide not to take part, or withdraw at any time, this will not affect the care you are receiving in any way.

What is the purpose of the study?

We are a group of scientists, midwives and doctors who work in the Institute of Reproductive and Developmental Biology at Imperial College London. We are working together to improve our medical and scientific knowledge of pregnancy, and pregnancy complications.

We are researching how the placenta (afterbirth) and the immune system work together during pregnancy to ensure the growth and development of a healthy baby. It is hoped that in the future, this research could help us understand how we can improve care for women experiencing complications in pregnancy.

Why have I been chosen?

We may ask you to participate as you have had a healthy pregnancy, and are undergoing an elective caesarean section for delivery of your baby.

Do I have to take part?

Your participation is voluntary. If you wish you be part of the study, we will ask you to complete a consent form when you attend the procedure for your procedure. You will be given a copy of this consent form to keep, along with this information leaflet. If you decide to take part, you are free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive in the future.

What will happen if I take part?

If you agree to participate, we will ask you to give your placenta (afterbirth) for our research following delivery of your baby. Usually, the placenta is discarded after delivery. We will take some blood from the umbilical cord of the placenta. We will not take any blood from your baby.

We may also ask you to give a sample of blood. This sample will be less than 4 teaspoons (20ml) Where possible, we will collect this when blood is being taken as part of your routine medical care. We may also access a sample of your blood which was already taken and stored at the start of your pregnancy when you were booked in for antenatal care.

You have the option to just donate your placenta, if you wish.

The research midwife will look at sections of you, and your baby's medical notes where it is relevant to you taking part in the research, and record some non-identifiable information about the birth, and the health of you and the baby.

What are the possible benefits of taking part?

Taking part in the study will not modify your treatment. We hope that pregnant women and babies in the future will benefit from your participation and information we gain from this study.

What are the possible disadvantages/risks of taking part?

If you give a blood sample, you may experience some discomfort from the needle while your blood is taken, but we will try to collect the research sample at the same time as your routine blood samples.

What will happen to the data and samples collected?

The data and samples will be used to carry out research into the immune system during pregnancy, and how the placenta works to support the developing baby. The samples will be anonymously stored in a secure laboratory and some samples will be analysed over the next 5 years at Imperial College, and at collaborating academic institutions. If you agree, at the end of the study, the samples will remain in the laboratory and may be used for other ethically-approved research projects on pregnancy. If you do not agree for your samples to contribute to future ethically-approved studies, your samples will be destroyed. The study data will be kept securely for 10 years.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are 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 have been treated during the course of this study then you should immediately inform the Principle Investigator (Beth Holder; b.holder@imperial.ac.uk; 0207 594 1773). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

What will happen to the results of the research study?

The results from the research will be published in scientific and medical journals. These will all be open access, which means that anyone can read them. We will also share our results by presenting at scientific conferences. We will post study updates on our website, including links where you will be able to read any of our publications and outreach activities (link on back page).

You will not be identified in any report/publication.

Who is organising and funding the research?

Imperial College London is the sponsor for this study. Funding for the research has come from the National Institutes for Health, and from the IMPRINT network (funded by the Medical Research Council, Biotechnology and Biological Sciences Research Council).

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by Yorkshire and the Humber-Sheffield Research Ethics Committee.

Will my taking part in this study be kept confidential?

Your name and NHS number will be recorded on the consent form so that we can collect your sample. Your address will not be recorded. A copy of your consent form will be put in your medical notes, and one will be stored in a locked cabinet, securely on Imperial College premises. Your name will be removed from the information when it is shown to staff outside the study.

Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will therefore securely keep identifiable information about you:

- 10 years after the study has finished in relation to data subject consent forms
- 10 years after the study has completed in relation to primary research data

Further information on Imperial College London's retention periods may be found at <https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf>. You can also find out more about how we use your information by contacting the Principal Investigator on this study (contact information on the back page)

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

LEGAL BASIS

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.

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.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

CONTACT US

If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied 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). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

DATA COLLECTION AND HANDLING

Imperial College will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Imperial College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Imperial College NHS Trust will pass these details to Imperial College along with the information collected from you and/or your medical records. The only people in Imperial College who will have access to information that identifies you will be people who need to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number, or contact details. Imperial College London will keep identifiable information about you from this study for 10 years after this study has ended in a secure location.

Where data is intended to or likely to be used for future research

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with 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. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Thank you for your participation in the COMET study

Contact for further information

If you have any questions at any stage, please do not hesitate to contact us:

Study phone: ____0207 594 2137____

Sara Barnett, Research Midwife
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Tel: 0207 594 2137____

Beth Holder, Principal Investigator
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0207 594 1773

Women's Health Research Centre,
c/o Imperial College London,
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Updates to the study will be posted on the website:
www.theholderlab.com/info

