Participant information for mums-to-be
The Baby Biome Study

You are invited to participate in a study called the Baby Biome Study. This information sheet gives details about what taking part involves.

Before you decide, it is important you understand why the research is being done and what it will involve. Please take time to read the following information and discuss it with your family and friends if you wish. If you have any questions please speak to your midwife.

What is the Baby Biome Study?

The Baby Biome Study is an important research study that aims to find out how microbes (bugs) such as bacteria and viruses influence a baby’s immune system in the early years.

We are exposed to microbes, good and bad, throughout our lives. These microbes are in our mouth, on our skin and in our digestive and reproductive tracks – the good ones are vital, helping us to digest food, producing needed vitamins and fighting bad microbes. These bad microbes are harmful and can make us sick and also possibly cause asthma or allergies.

Our immune system defends us against these harmful microbes. This study seeks to understand how microbes interact with our immune system in the early years and find out why we stay healthy, and why we sometimes get sick.

Why me?
The Baby Biome Study is working in partnership with University College London Hospitals (UCLH) NHS Foundation Trust and we are inviting all expectant mothers, giving birth at UCLH to take part.

What would you like me to do?

Donate some biological samples
If you would like to take part in the Baby Biome Study we will ask you to donate some samples that would otherwise be thrown away.

Your midwife will help you collect the samples below during and after your baby’s birth. They won’t do this until they’ve made sure your baby is safe and healthy.

1. **Poo**; can tell us a lot about the kinds of microbes different people have, we’d like you to collect this before or after birth or a midwife can collect this during labour.

2. **Vaginal swab**; shows us the microbes that your baby has been in contact with during birth which may be passed on to your baby, we would like you to self-collect this sample before birth.

3. **Cord blood (and placenta at some hospitals)**; help us understand how a baby’s immune system develops from before they are born. The midwife will collect both samples after birth.
4. **Let us find out some information;** about your pregnancy, labour and birth – such as whether your baby was born vaginally or by caesarean section and details about any antibiotics you or your baby may have received at hospital. This will help us understand if antibiotics or the way mothers give birth influences what microbes their babies develop.

Before you are discharged or when you are on the postnatal ward we will ask you to sign a consent form and we’ll give you a small pack to take home, which includes:

- Poo collection kit
- Pre-paid envelope
- A brief form asking about feeding & antibiotics

5. **7 days after birth;** we’ll ask you to collect and post a sample of your baby’s poo to us in a contained in a pre-paid envelope so we can see what microbes they have developed. We’ll also ask you to send back a short information form on what your baby has eaten and on any antibiotics given to you or your baby. We’ll remind you to return your baby’s poo to us by sending a text or by phoning you.

**What happens if my baby is still in hospital after 7 days?**

If you would still like to take part, one of the Baby Biome Study team will collection a poo sample from your baby’s nappy.

We will also ask a group of mums to send us two additional samples of their baby’s poo. If you are selected and agree, we’ll ask you to send us your baby’s poo at 4, 7 and 21 days after birth.

We will also ask you to let us retrieve leftover samples you gave during your pregnancy and leftover blood from tests your baby will have after birth. These samples are routinely collected so we won’t be collecting anything extra from you or your baby and they will otherwise be discarded in due course. These samples will help us to find out whether any infections you may have during pregnancy affect how your baby’s immune system works at birth.

**Let us collect health-related information**

The Baby Biome Study is trying to build a picture of how our experiences as babies shape our lives. Some of the most important information about yours or your baby’s health is about events that might happen in the future, such as your baby developing asthma during childhood.

As part of our research we would like your permission to collect basic information about you and your baby from your medical notes around the time of birth, and to link to information from records that are already held by the NHS and other similar organisations.

The types of health information we will ask to link to include visits to your doctor or the hospital and any health conditions you or your baby have. This information can help us understand how a mother’s health during pregnancy affects a baby’s health when born and during childhood.

**Are there any benefits of taking part?**

Some women say they enjoy taking part in research that may help other women and their babies in the future. Although there are no direct benefits to you or your baby, the samples you provide will help researchers and doctors understand more about the immune system and microbes, which in turn could help us develop ways to fight bad microbes.
Your data and confidentiality

We value the contribution you make by donating your samples and sharing your information with us and we are very careful to keep all of your information confidential and secure.

Our promise to you

1. We separate your personal details – your name, address and contact details- from the other information you give us including your answers and samples.

2. At no point will your personal details be included in the data made available to researchers, other than those in the Baby Biome Study team. No one using the data will know who the information has come from, or who is in the study.

3. All the information we collect will be held securely in accordance with the Data Protection Act 1998 and all samples will be stored in a facility licensed under the Human Tissue Act 2004.

4. The information you provide will be used for research purposes only.

How will the information I provide be used?

We need to store samples and information long-term so that researchers can use them in the future. Long-term means for many years to come (more than 10 years).

The Baby Biome Study team at University College London Hospital will collect the samples you have donated. Once we have linked your sample to the details from your medical notes on your pregnancy and labour we will remove any personal identifiable information and replace it with your anonymous participant number.

Once your samples have been anonymised we will send them to our partner laboratories outside of the hospital, where we will store them until research is being carried out.

Will I find out the results of any tests on the samples I donate?

The tests we carry out are not done for clinical reasons. Also, we do not carry out tests on the samples you provide immediately as we wait until we have enough samples so we can test them in groups. Many of the samples will be used in future research. Because of this we cannot tell you the results of tests. The information you provide will only be analysed for groups and not for individuals.

All the findings from the Baby Biome Study will be available on our website http://www.ucl.ac.uk/babybiome-study where you can sign up to receive updates on our important findings about child health.

Do I have to take part?

No, you do not have to take part. You can choose whether you want to take part. Even if you agree to take part around the time of your baby’s birth, you can withdraw your information at any time. If you decide not to participate, your and your baby’s healthcare will not be affected. If you would like to withdraw call our Baby Biome Study midwife on 07958 228 818.

If you decide now that you do not want to take part, please tell your midwife who will put a sticker on your maternity notes so that you are not asked again about whether you would like to take part.

Keeping in touch
You will be given this leaflet to take home with you when you leave the hospital after you have had your baby so that you can contact us in the future if you wish to do so.

The Baby Biome Study wants to understand how early life experiences influence health and wellbeing later in children’s lives. With your permission we would like to get in touch with you in future and may ask you to take part in future Baby Biome Study activities. When we get in touch we’ll send you information about these activities. Of course, it’s up to you whether you answer our questions or agree to participate further.

Find out more

If you have any questions or would like to find out more about the Baby Biome Study please contact one of our research midwives on 07958 228 818 or email UCLH.researchmidwives@nhs.net. You can find out more about the Baby Biome Study on our website http://www.ucl.ac.uk/babybiome-study.

If you have any concerns you can talk to Patient Advice and Liaison Service (PALS) at your hospital, you can phone them 0203 447 3002 or email PALS@uclh.nhs.uk.

Who’s behind the Baby Biome Study?

Collaboration
The Baby Biome Study team is based at University College London and collaborates with researchers and academics from across the UK. We are also working with Barking, Havering and Redbridge University Hospitals NHS Trust and University Hospitals Leicester NHS Trust to help make the study a success.

Funding
The Baby Biome Study is funded by the Wellcome Trust.

Who is directing the Baby Biome Study?
The Director of the Baby Biome Study is Professor Peter Brocklehurst. If you would like to write to Professor Brocklehurst please send your letter to Institute for Women’s Health, Medical School Building, 74 Huntley Street, WC1E 6AU.

Ethical Approval
The Baby Biome Study has been approved by the NHS London – City and East Research Ethics Committee (REC reference 12/LO/1492).