Privacy Notice for the Baby Biome Study (BBS)

The Baby Biome Study (BBS) is a research study that aims to find out how microbes, such as bacteria and viruses influence a baby's immune system in the early years. 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. The BBS is trying to build a picture of how our experiences as babies shape our lives.

The BBS is a proposed large-scale UK birth cohort study and biobank, with longitudinal follow-up through electronic health data linkage to undertake ground-breaking research in this field. The overall aims of the full study are to investigate the relationships between infant microbiota and the immune system, environment, clinical and feeding practices and subsequent health outcomes. This study has been funded by the Wellcome Trust and University of Birmingham.

University College London (UCL), University of Birmingham (UoB), University Hospitals Birmingham (UHB) NHSFT, University Hospital of Leicester NHS Trust, University College London Hospitals (UCLH) NHSFT, Barking, Havering and Redbridge University Hospitals (BHRUT) NHS Trust, and the Wellcome Trust Sanger Institute are running the evaluation collaboratively. The BBS team is based at UCL.

Data Controller: University College London (**UCL**) – London & University of Birmingham (**UoB**) – Birmingham

Data Protection Officer: Robert Aldridge – r.aldridge@ucl.ac.uk, David Law – D.A.I.Law@bham.ac.uk

Data Processor: University College London (**UCL**) – London & University of Birmingham (**UoB**) – Birmingham & University Hospitals Birmingham NHS Foundation Trust – Birmingham (**UHB NHSFT**)

For clinical matters, please contact your hospital's clinical team. If you would like to discuss anything else relating to the BBS evaluation please contact:

Dr Nigel Field
UCL, Centre for Molecular Epidemiology and Translational Research
nigel.field@ucl.ac.uk**,**
Telephone: 020 3108 2092

Supervisory Authority:
UCL & Sanger Institute

Lawful Basis:
Article 6(1) (e): processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller
The lawful basis for data processing under Article 6, for this project, is public task and consent.

As per Article 9, special category data collected includes: health. The condition applicable, as listed in Article 9(2) (j): processing is necessary for archiving purposes in the public interest, scientific, or historical research purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

The same legal basis is relied upon for all collaborators involved in the study.

In order to send out the consent form and collect patient information the study needs to access personal data. This privacy notice explains what personal data we are processing and why.

Where we collect information about patients

Participation in the study will be kept confidential. Ethical and legal practice will be followed and all information about you will be handled in confidence.

We collect information about patients in two ways:

- When patients give information to us **DIRECTLY**

Women will first be made directly aware of the opportunity to take part in the BBS during pregnancy at around 12 weeks' gestation at booking; a flyer will be placed in the notes. Women will be provided with location specific Patient information Sheet (PIS) during pregnancy by their community midwife which will explain the study and advises women that they may be approached to take part when they come to the labour ward to give birth.

A member of the clinical team directly involved with the patient's care will explain the rationale of the study to the patients. This will most likely be labour ward midwives. Upon arrival at the hospital, labour ward midwives will provide those women who have not heard of the study with a PIS. Midwives will speak further to women after delivery of their baby, once clinically stable, and before discharge from the labour ward. Women will have had a chance to review the PIS and midwives will offer to answer questions and go through the PIS with them if they wish.

Women who have declined being in the BBS will have a sticker placed on their record, and will not be approached again.

 When patients give information to us **INDIRECTLY**

For the longitudinal study, recruited patients are required to give their informed consent to collect and record their clinical and treatment data into a database specifically holding BBS data. One of the data processors, UHB, will be linking patient level data to the Hospital Episode Statistics (HES) and Mortality (death) datasets, disseminated by NHS Digital, to the database to capture a more comprehensive dataset of the patient's clinical episodes. NHS Digital disseminates HES data, which contains the details of all patient admissions, A&E attendances, and outpatient appointments at NHS hospitals in England, as well as the Mortality (death) data occurring in England. In order for the data processor to collect pseudonymized patient data, access to the patient records collected and recorded by UCL is needed. All data transfers will be sent securely.

What personal data will be collected and how will it be used?

This study aims to collect information about clinical outcomes in mothers and babies to understand more about the immune system and microbes, which in turn could help develop ways to fight bad microbes.

More specifically a number of biological samples will be required from the mother, during and after the birth of the baby, as part of the BBS:

1. Poo – collected before or after birth or midwife can collect during labour
2. Vaginal swab – self-collected before birth
3. Cord blood (and placenta at some hospitals) – midwife collects both after birth
4. Other information – about pregnancy, labour, and birth
5. Brief form asking about feeding and antibiotics

A week after birth, a poo sample is also collected from the baby.
Leftover samples given during the pregnancy and leftover blood from tests baby has had after birth may also be used. Biological samples are sent to an accredited laboratory for initial processing, aliquoting and storage, before being sent to the following sites for storage and/or analysis, all labelled with study identifiers (i.e. not with personal identifiers). Stool, vaginal swabs, and cord blood samples will be transported in batches to the Sanger Institute and UCL Cruciform building, respectively, once a sufficient number of samples have been collected.

In addition to the biological samples, health-related information will be collected for mothers and babies. Basic information about mother and baby's health will be collected from medical notes around the time of birth, and will be linked to other NHS held records. The types of health information asked to link to include: doctor or hospital visits, any health conditions mother or baby have, etc. This information can help us understand how a mother's health during pregnancy affects a baby's health when born and during childhood.

There are two central data warehouses where patient data is stored, one within UCL (which stores the study dataset on the UCL Datasafehaven), and one within UHB. These data warehouses will hold all the information required for the study to be able to successfully answer the questions needed. Data from the recruiting centers will feed

clinical and observational data into the UCL data warehouse. UCL will then send the identifiable data to UHB, at which point UHB will store in their warehouse, on their servers. UHB will then hold the identifiable information needed for linking their data to NHS Digital. UHB then sends this data to NHS Digital to be linked to HES/Mortality datasets. NHS Digital will then send pseudonymized data back to UHB, who will then send this off to UoB/UCL for further processing/analysis, at pseudonymized level. All access to patient data will be managed whilst adhering to strict protocols.

At UCL, all patient information is stored within the datasafehaven, which is a "walled garden" protected site. At UHB, all patient information will be stored on password protected computers and will only be accessible to the named individuals on the team who will be carrying out analysis of your data. When the results of the study are reported, individuals who have taken part will not be identified in any way. All data processing will take place in line with the requirements of the data protection legislation.

Biological samples and information will be stored long-term (more than ten years) so that researchers can use them in the future.

How can patients opt out of the study?

Patients who decide not to participate in the study are free to decline or withdraw at any time, without giving a reason. This does not affect the standard of care you receive.

Patients can withdraw or opt out of the study at any point of time by contacting their midwives, nurses, clinicians at the NHS Trust where clinical care is provided to them. Patients have the right to erasure, also known as the right to be forgotten. The following contact details can be used to withdraw, opt out, or be forgotten:

		PALS/PILS Department
• **University College London (UCL)**	Dr Nigel Field nigel.field@ucl.ac.uk	
• **University of Birmingham (UoB)**	Professor Peter Brocklehurst	
• **University Hospitals Birmingham NHSFT**	Suzy Gallier & Sandy Sahdra STAAR@uhb.nhs.uk	
• **University Hospitals of Leicester NHS Trust**	07944 244 661 0116 204 7813	08081 788337 pils@uhl-tr.nhs.uk
• **University College London Hospitals NHSFT**	07958 228 818 UCLH.researchmidwives@nhs.net	0203 447 3002 PALS@uclh.nhs.uk
• **Barking, Havering and Redbridge University Hospitals NHS Trust**	Helen.Smith@bhrhospitals.nhs.uk Rachael.Connolly@bhrhospitals.nhs.uk	01708 435 454 pals@bhrshospitals.nhs.uk
• **Wellcome Trust Sanger Institute**		

Reporting plans

The data generated will be used for peer-reviewed publication in relevant journals and conferences, and informing public health policy. Results will be presented at national and international scientific conferences focusing on child and maternal health, infectious disease and the microbiota. Examples of possible conferences include: the World Antimicrobial Resistance Congress and the Conference of the Association of Maternal and Child Health. Only anonymised, aggregate data will be presented. Reported results will not contain any patient identifiable data.

This initial feasibility stage will test whether it is possible to link the data obtained from the approximately 3400 women, already consented to take part in the study. An evaluation will reveal each datasets' limitations and benefits, and the possibility of data linkage as the patient cohort expands. This data will be used to provide evidence for an application for funding for an expansion of this study to undertake recruitment of approximately 80,000 mothers and their babies.

What if there is a problem?

If you have a concern about any aspect of this study, there are a number of sources you can speak to, including: clinicians and researchers at your NHS trust, the Scientific Lead - Dr Nigel Field, nigel.field@ucl.ac.uk, 020 3108 2092 or by post:

Centre for Molecular Epidemiology and Translational Research
Mortimer Market Centre
Off Tottenham Court Road
UCL
WC1E 6JB

Alternatively, you can write to the Director of the BBS:

Professor Peter Brocklehurst
Birmingham Clinical Trials Unit
105, Public Health Building
Institute of Applied Health Research
College of Medical and Dental Sciences
University of Birmingham
Edgbaston, Birmingham
B15 2TT

If you remain unhappy and wish to complain formally, you can do this through your local hospital's Patients Advice and Liaison Service (PALS) or Patient Information and Liaison Service (PILS). Please contact your hospital for the contact details to their PALS department.