

Summary Participant Information Sheet.

We invite you to take part in a research study called

The **PEARL** Study *Pregnancy and EARLY Life*

Before you decide whether 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 relatives and friends if you wish. You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you get from your own doctors.

This is a summary sheet of the study and a full version is available if you would like to know more.

Why are we doing this study?

We would like to better understand how food and the gut microbiome (beneficial bacteria, fungi and viruses that live in our gut) are linked to the promotion of health and the prevention of disease.

The specific aim of The PEARL Study is to better understand the role of the gut microbiome during early life. Pregnancy and the first years of life are when the microbiome establishes, setting the foundation for future health. Understanding this will help us identify ways to improve lifelong health and wellbeing.

What will I need to do if I take part?

In order to take part, you need to be **no more than 22 weeks pregnant** at the time of consenting to the study and be in good general health. The study will last approximately 31 months and will involve you during pregnancy and your new baby. The study is divided into 3 phases and will require you to collect you and your baby's own samples and swabs and complete some questionnaires please.

We will supply you with a small freezer (approximately 51 x 44 x 47.5 cm {H x W x D} and weighing approximately 15.5 kgs) for the course of the study, to keep your samples in for each time point until a member of the Research team collects them from you at home. This will be within 4 weeks of the sample collection point. When we collect your frozen samples, we will also drop off your next collection pack containing everything you will need for your next set of samples. At the end of the study, the freezer is yours to keep and we will also send you a £20 Love2Shop voucher for your time and any inconvenience. If you no longer wish to keep the freezer, a member of the research team will come and collect it from you.

Phase 1

During pregnancy (12 weeks, 23 weeks & 30 weeks) (Plus an extra 7 days).

In the comfort of your own home at the above 3 time points, we would ask that you take a skin swab of your arm, a low vaginal swab (which is safe and very easy to do), provide a stool (poo) and urine sample. We would also ask you to complete two questionnaires at the middle time point above. At the same middle time point, we would request that you complete a third questionnaire relating to personal food choices, but this

questionnaire is entirely optional. Please note: If you are beyond 14 weeks of pregnancy (but less than 22 weeks) you can still take part. Your first collection will therefore be by 23 weeks.

We will provide you with your collection packs and instructions how to collect each sample.

When you have routine pregnancy blood tests at the Norfolk & Norwich University Hospital (NNUH) or with the Community Midwife, we would request one extra 4ml sample (less than one teaspoon). **This is optional. We request that you let us know if you have given a blood sample for research purposes.**

We will send you text reminders 1 day before each collection time point throughout the study to remind you when to take your samples and store them in your sample freezer. When your samples are ready to collect we would ask you to reply to the reminder message saying "Done" so that we know they have been taken. We will also send you a text 1 week before we will be picking up your samples (pre-arranged date) so you will have a reminder of when this will be. You will also receive another reminder message the day before.

Phase 2

Labour/birth (plus an extra 7 days after giving birth).

We would sensitively request a low vaginal swab at a convenient time during labour (for a vaginal delivery) or just after delivery (if you are having a Caesarean Section). A 2ml sample of umbilical cord blood (just after giving birth) will also be requested. **This is optional.**

Within the first 7 days after giving birth we will also ask you to provide another skin swab and stool and urine sample. These could be provided either before discharge or collected from home by Researchers, as in phase 1. In addition, we would ask you to collect your baby's first poo sample (meconium) and a skin swab from their arm. If you are breast feeding and produce enough colostrum/milk, we would also request about 1ml. **This is also optional.**

1 week after giving birth & 3 weeks after giving birth (plus an extra 7 days).

At 1 and 3 weeks after giving birth, you will again be asked to collect a skin swab, low vaginal swab and a stool and urine sample from yourself. In addition, if you are breast feeding and produce enough milk, we would also like to collect up to 5mls (up to one teaspoon) of breast milk. **Again, this is optional.** A skin swab and a stool sample from your baby will also be requested. These will either be collected by you if you or your baby are still in hospital or collected at home after you are both discharged. There will also be a questionnaire about your baby to complete.

We have thought about this very carefully and realise that this is going to be a tiring and emotional time for you (and the person who is supporting you). For this reason, we have allowed extra time (an additional 7 days) for the collection of samples and swabs at each of the Phase 2 time points.

All the Phase 2 packs (Birth, Week 1 and Week 3) will be picked up together at the end of Week 3 and your Month 4 pack dropped off.

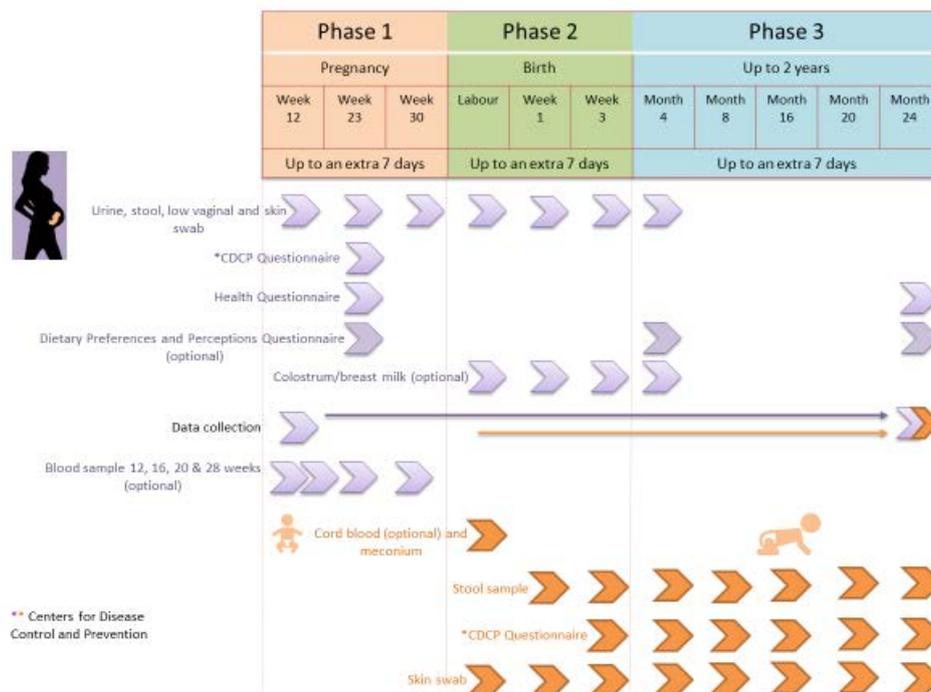
Phase 3

4, 8, 16, 20 & 24 months after giving birth (plus an extra 7 days).

The same samples and swabs as in Phase 1 from yourself and a stool sample and skin swab from your baby will be requested at 4 months. At 8, 16, 20 and 24 months, we will just request a stool sample and a skin swab from your baby and there will be some questionnaires to complete. For all Phase 3 collection time points, you will have an extra week to collect you and your baby's samples, swabs and questionnaires.

We would also like to collect some data held with your GP and the hospital from you during your pregnancy and your baby up to 24 months so that we can record any events, like infections etc.

The flow chart below describes all the collections and time points over the 31 months. We will go through the study in detail using the Full Participant Information Sheet and answer any questions you have once you have expressed an interest in the study. Our contact details can be found below.



What do I need to do next?

For further information you can contact Shelina Rajan, the Clinical Studies Officer for this study by phone or e-mail below. Alternatively, you can view the Full Participant Information Sheet online as well as register your interest online. Any personal information you provide online will be in line with the General Data Protection Regulations and the Data Protection Act 2018.



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Thank you.