

Summary Participant Information Sheet

Project Title:

Pregnancy and early life (PEARL study)

Invitation:

We are looking to recruit 250 participants who are under 22 weeks pregnant to take part in a research study. Below is a short summary of the study. Please ask for the full participant information sheet if you would like to know more. 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.

What is the purpose of the study?

All of us have trillions of bacteria and other beneficial microbes in our guts. Collectively they are called the 'microbiome' and they play a critical role in protecting our health, right from the earliest moments of life when a baby is growing in the womb. They help us with digesting our food and even with programming our immune systems so that we can fight off infections. Anything that affects successful microbiome establishment can have knock-on effects on health in later life.

The data we collect as part of the PEARL study will enable us to better understand how a 'healthy microbiome' establishes in early life, and what factors influence it most strongly. The results will provide the evidence needed to develop safe new therapies to enable a 'healthy microbiome' in early life. This would be a big step towards providing all babies with the best start in life.

We need your help to achieve this, and sincerely hope that you will consider taking part.

What do I have to do if I take part?

Once you are enrolled, we will ask you to collect a few samples from yourself and your baby throughout pregnancy and during the first 2 years after the baby is born. There are 12 timepoints that we would like to collect them from you in total.

Sample collection has been designed to be as easy as possible for you during this busy time, including sample pick up from your home by our research team, at 4 points throughout the study, so you don't have to go anywhere to drop off your samples. Family and friends are very welcome to help you collect samples too.

We will also ask you to complete some questionnaires at some of these timepoints. Details of which samples we will ask for at each time point is shown in the table below.

We will provide you with a small benchtop freezer to store your samples until the research team can collect them from you at your home. At birth, you can either take your samples at the hospital or once you get home. If you take the samples at the hospital (NNUH only), you can give them to your midwife who will store them for you until they are collected by the research team.

Samples collected from participants' homes by research team												
Phase 1 (pregnancy)				Phase 2 (birth)			Phase 3 (following birth)					
Trimester 1 (week 12)	Trimester 2 (week 23)	Trimester 3 (week 30)	At birth	Week 1	Week 3	Month 4	Month 8	Month 12	Month 16	Month 20	Month 24	
Informed consent up to 22 weeks												
Mother's samples	Urine	✓	✓	✓	✓	✓	✓					
	Stool											
	Low vaginal swab	✓	✓	✓	✓	✓	✓					
	Skin swab											
	CDCP questionnaire		✓									
	Health questionnaire		✓								✓	
	Dietary questionnaire (optional)		✓								✓	
Colostrum/ breast milk (optional)				✓	✓	✓	✓					
Blood samplesn (optional)	Please provide samples at 12, 16, 20 and 28 weeks if you can											
Baby's samples	Stool, meconium and skin swabs				✓	✓	✓	✓	✓	✓	✓	
	CDCP questionnaire				✓	✓	✓	✓	✓	✓	✓	
	Cord blood (optional)				✓							

¹Centre for Disease Control & Prevention ²Participant Dietary Preferences and Perceptions Questionnaire ³Data collected from Primary and Secondary Care records by GP Data Manager and Study Researcher

CORONAVIRUS UPDATE: While the UK government recommend social distancing measures to prevent the spread of coronavirus, we will be implementing a few changes in the way we run the PEARL study. We will not collect samples from participants homes until we are assured that it is safe to do so. We will send sample collection packs to participants in the post, and we ask that participants continue to collect their samples and freeze them until the research team are able to arrange a collection once the social distancing measures are relaxed. We will continue to send text reminders when your samples are due to be taken. We apologise for any inconvenience this may call while we are working in these unprecedented circumstances.

Please do not collect any samples and inform the study team if you or anyone in your household has:

- symptoms of coronavirus (COVID-19) infection and are currently awaiting a test result
- tested positive for coronavirus (COVID-19)
- had recent contact with someone who has coronavirus – ensuring you self-isolate if the NHS test and trace service advises you to do so.

Data collection

In addition to these samples/questionnaires, we would like to collect health information which is collected as a part of your routine pregnancy care and from health visitor checks once the baby is born. You would not need to do anything to collect this information apart from provide your consent for us to access your records.

What should I do now?

If you are interested in taking part in the study and would like to know more, you can speak to the research team on 07876182564/pearl@quadram.ac.uk, or go to the study website <https://quadram.ac.uk/pearlstudy/> and complete the expression of interest form.

Thank you for taking the time to read this information.

This document has been approved by the Dulwich Research Ethics Committee.