

# Supplementary Participant Information Sheet: Microbiome

## Children Growing Up in Liverpool Longitudinal Birth Cohort

This is a supplementary information sheet about how the Children Growing Up in Liverpool (C-GULL) study will look at the link between gut health and mental health. We provide information about how to collect samples at home, such as stool (called poo from here) and breast milk, and about the questions we'll ask about nutrition and feeding.

We understand that you may not have decided how you are going to feed your baby yet, and that plans for feeding can change once baby is born. We hope to collect information and samples from you and your baby no matter how you plan to or end up feeding your baby.

Thank you for reading this.

### Why are we doing this study?

We know that the first months of a baby's life are extremely important for how the brain develops, and that this can have a long-lasting impact on a person's mental health. That's why we want to find out more about what influences early brain development.

New research suggests that the bacteria in our gut, which themselves are influenced by things like how we are born, where we live, what medicines we take and what we eat and drink, play an important role in our brain development and mental health. Yet, there is still much we don't know about how this happens.

By collecting breast milk and poo from mothers/birthing parents and babies, we aim to find out more about how these things are linked. We want to use cutting-edge technology to better understand how gut bacteria, breast milk, formula milk and other factors are linked to mental health outcomes.

Our big goal? To find ways to stop mental health problems before they even start. This could be simple things like changing what we eat or using "good" bacteria (probiotics) to boost the healthy bacteria in children's guts and perhaps protect their mental health and well-being ensuring a brighter and healthier future for all.

### What are we doing?

To understand more about the role of gut bacteria and the food we eat as babies, we plan to collect poo samples from babies and mothers/birthing parents. If babies are being fed with breast milk, we would also like to collect a sample of this. We will test these poo and breast milk samples in a laboratory, and link information about the bacteria in poo, and the nutrients in milk, with the other information we are collecting. This will help us figure out what might cause mental health problems, so we can find ways to prevent or treat them.

### Do I have to agree to this?

No, you do not have to agree. It is entirely your choice whether to participate in this part of the study or not. If you are already involved in the C-GULL Study, you can continue without providing these samples if you prefer. Your participation in any research study should always be voluntary, and you have the right to decide how much or how little you wish to contribute.

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### What will you collect and how?

Here is what is involved in collecting the samples:

**For babies:** we would like you to collect a small amount of poo at different times after they're born: when they're 7 days old, 1 month old, 12 months old, and 2 years old.

To collect your baby's poo, a kit with a small scoop will be provided so you can take a small amount, about the size of a 50p coin, from your baby's nappy. The kits will be given to you at one of your visits to Liverpool Women's Hospital or sent to you in the post. Once collected, the poo will go into a package that can be placed in a normal post box to be returned to us.

**For mums/birthing parents:** we would like you to collect a sample of your own poo around the time you give birth. Your own poo sample can be collected either at home; with a kit that will be given to you during your second visit to the research centre, or, if you prefer, at the hospital around the time of birth.

For those who are breastfeeding, we would also like you to collect a small amount of early breast milk (called colostrum) in the first three days after birth, and to collect a small amount of breast milk at 7 days, 1 month, and 3 months after birth, making sure this does not affect your baby's feeding. You can give as many or as few of these samples as you choose.

To collect colostrum, you will be asked for 0.5-2ml (less than half a teaspoon) that can be manually expressed into a provided tube. To collect breast milk, you will be asked for about 10-20ml (2-4 tablespoons) using a clean pump. We will provide you with a pump. The milk collected will go into a special tube, that we will provide, and be kept in your freezer at home until we can arrange a convenient time with you to collect it.

For each poo and each milk sample, we will give you a £10 gift voucher to thank you for your time.

### What help will I get to collect the sample and send it to the C-GULL team?

If you decide to take part, we will make it as easy and convenient as possible by giving you clear information and simple-to-use kits to help you collect your and your baby's samples. You can get in touch with us at any time if you need help or have any questions. We will also work with you to arrange a convenient method for returning the samples, whether it's through the post, home collection, or drop-off locations. Your comfort and ease of participation are our priority.

### What happens to my sample?

We will make sure all the samples you and your baby provide are carefully tracked, so we know exactly where they are. We will store some of your sample in Liverpool and send some to specialised laboratories in Cambridge, UK and Manitoba, Canada for analysis to learn more about the bacteria in the gut and the nutrients in breast milk. All samples will be coded and stored separately from any personal details (name, date of birth, contact details etc.) you provide to us. To make sure your samples are handled properly and ethically they will be stored in a facility licensed under the Human Tissue Act 2004 (England and Wales).

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### Can I change my mind?

You can ask for your samples to be destroyed if you no longer wish for them to be used, or if you withdraw from the C-GULL study. If you do decide that you no longer want us to use samples from you or your child, then you can contact us ([cgullstudy@liverpool.ac.uk](mailto:cgullstudy@liverpool.ac.uk) or 0151 795 6700) and request this. You do not need to give a reason. You can still participate in the C-GULL study if you decide you no longer want to give poo and breast milk samples.

### Will I find out the results from the tests carried out on samples that I give?

The C-GULL Study will not feedback any results from tests on samples taken as part of the study because:

- the milk and microbiome tests will produce results that are not used by doctors for their patients and we do not yet understand their meaning in terms of future health.
- tests are not done on all the samples immediately - so it may be a long time (years) before some of your samples are tested.

### Where can I find further information?

If you have questions or want to know more about the samples being collected as part of the study, please talk to the C-GULL Research team at Liverpool Women's Hospital. Please contact us on [cgullstudy@liverpool.ac.uk](mailto:cgullstudy@liverpool.ac.uk) or 0151 795 6700. You can also visit our website [cgullstudy.com](http://cgullstudy.com). We're here to help and make sure you and your baby have the best experience.

Thank you for taking the time to read and consider this information sheet.