

Supplementary Participant Information Sheet: Taking Part in the Study

Children Growing Up in Liverpool Longitudinal Birth Cohort

This is a supplementary information sheet to provide more information about what will happen if you decide to take part in the Children Growing Up in Liverpool (C-GULL) Study. Before you decide whether or not to take part it is important for you to understand why the study is being performed and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. A member of our research team will be happy to go through the study information with you and answer any questions you may have.

Thank you for reading this.

Why are we doing the study?

The C-GULL Study is an exciting new research study focused on improving the health and wellbeing of children and their families in the Liverpool City Region. It is the first new longitudinal birth cohort to be funded in the UK for almost 20 years. Longitudinal birth cohorts are large studies of babies born around the same time and followed up for many years. They are important as they can help us understand the connection between poverty, pregnancy and childhood, and the later development of illness. The C-GULL Study will collect information, including samples and data, from 10,000 children and their families, starting in pregnancy and continuing throughout life.

Why are we interested in pregnancy?

Understanding more about this time, will help us understand how early life experiences shape health and wellbeing later on. The C-GULL Study will support a wide range of research designed to understand how to give every child the best possible start in life. There have been several research studies similar to the C-GULL Study across the UK. These studies have recorded the childhoods and adult lives of different generations growing up in the UK. Babies in the earliest study are now well into their sixties and they continue to help researchers understand the importance of childhood experiences and how making a difference to children's lives today makes a difference to their future lives as adults.

The C-GULL Study will focus on the lives of a new generation of children growing up in the Liverpool City Region. It is also different to previous studies in some important ways. Unlike most other studies, the C-GULL Study will start in early pregnancy, creating an exciting new opportunity to understand how babies grow and develop from as early as possible. It is also the largest study of its kind so far, which means that we will be able to answer some research questions we haven't been able to before now using smaller studies.

From the information and samples we collect from the C-GULL Study children and their families, researchers may be able to understand more about things like:

- why some babies develop allergies and conditions such as asthma,
- how parental mental health can shape a child's long-term outcomes,
- the role of fathers and carers in shaping a child's development
- the impact of clean air and chemical pollutants in early life

Life in the UK is changing all the time and babies born today will have very different lives to ours and will live longer than their parents - one in five will live to be at least 100 years old! By making sure we involve all families, from different communities, cultures and backgrounds, the C-GULL Study will not only reflect the rich social and cultural mix of the UK

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today, but also help us understand how to give all children the best possible start in life. By taking part in the C-GULL Study you could make a difference to the lives of your children, your children's children and many generations to come.

What will happen if I decide to take part?

We will ask you to visit us (at our research centre in Liverpool Women's Hospital or in one of our community centres) three times: once in early pregnancy, once in late pregnancy and then when your baby is two years old. The visits may last up to two hours each. We will also ask you to provide us with some information when your child is 3 months and then 12 months of age. We will do this by email, text or by sending you a letter - whatever method is best for you. With your permission, we will also collect samples at each visit to the research centre during your pregnancy, around the time of delivery and following the birth of your baby.

We may wish to contact you and your baby again at some time in the future to answer other questions or attend for more visits. It is your choice whether to take part in these when you are contacted.

We would like to access information that the NHS and other organisations hold about you to allow us to understand about your and your baby's future health and wellbeing. This will help researchers get a more complete picture of how the information the C-GULL Study collects directly from you may be related to other events in your and your baby's life. This would only be done with your permission.

If you take part in the C-GULL Study you will be agreeing to have the anonymised information and samples you and your baby have provided stored by the C-GULL Study and used by researchers for many years to come.

- **The pregnancy visits**

You will have two visits to the C-GULL research centre during pregnancy, where you will see our dedicated C-GULL Research Midwives and other members of the C-GULL Clinical Research team.

Before you come, we will contact you and confirm your appointment either in a letter or by email. This will also include a checklist of the things that you will need to bring to your appointment with you. For example, a list of the medicines that you are currently taking.

When you arrive at your first visit, a member of the Research Midwife team will tell you more about the C-GULL Study and give you the opportunity to ask any questions that you may have. You can ask as many questions as you want before deciding whether to take part. If you decide to join the study, you will be asked to sign a consent form and will be given a copy of this to take home with you. During this visit we will ask you to answer some questions about your health, pregnancy, lifestyle, education, work and social support from your family and friends. We will also ask you to fill in a few questionnaires about how you feel and then the midwife will ask if they can take a few samples.

During your second visit we will not ask you to complete consent again, we will just ask you to answer a few questions, provide a blood sample and take a kit home to collect a small sample of your stool (poo). We will also give you some kits to collect samples from yourself and your baby at home after your baby is born. You will also get the opportunity to talk with a midwife again.

- **Around the time of my baby's birth**

We will not need to speak with you around the time of your baby's birth. This is a special time and we want to respect this. We will be able to access samples and information about you and your baby from the routine hospital procedures and records. If, however, you would like to speak with a member of the research team - we will be able to arrange this for you. If you consent to your baby having a body composition assessment in the PEA POD then a member of the

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research team will come and see you prior to your discharge from the hospital to arrange this. For more information about the PEA POD and what will happen to your baby, please refer to our Supplementary Participant Information: PEA POD.

- **The first year of my baby's life**

We will contact you by email, text or letter whichever you prefer, when your baby is around the ages of 3 months and 12 months. We will ask you to answer some questions about your and your baby's health. You do not need to come and see us at the research centre, these questions can be completed at home in your own time. If you should need some help with answering the questions our Clinical Research team will be able to support you. If you have agreed to give samples after your baby is born we will ask you to collect them from yourself and your baby at set times until your baby is 12 months (1 year) old.

- **The Two Year Follow-up Visit**

We will contact you around the time of your child's second birthday. This is a huge milestone and we would like to arrange for you and your child to visit us again at one of our community centres so that we can ask you some questions as well as play games and do some tasks with your child to see how they are growing and developing. These games and tasks allow us to see how your child is starting to learn and understand the world around them. We will also give you the opportunity to ask any questions you may have about your or your child's health and development. Around this time we will also ask you to collect the final sample from your child, if you have been taking part in this aspect of the study.

When are samples collected?

Samples will be collected at each visit to the research centre during your pregnancy and around the time you give birth. We would also like you to collect some samples from yourself and your baby at home after your baby is born. These samples can be returned to us by post, home collections or via drop-off locations.

What samples are you collecting?

We will ask your permission to collect samples from you when you visit the research centre during pregnancy. These samples include:

Visit 1 (early pregnancy):

- Blood (20-30ml or around two tablespoons)
- Hair (a small number of strands)
- Urine

Visit 2 (late pregnancy):

- Blood (20-30ml or around two tablespoons)

At this visit we will also provide you with a sample kit to take home and collect a poo sample if you agree to give one.

We will ask your permission to collect the following samples from you around the time of your baby's birth:

- some blood from the umbilical cord (cord blood),
- placenta (afterbirth),
- colostrum (first milk, surplus to feeding needs)

A Research Midwife will collect the cord blood and placenta samples for you - you won't have to do anything. You can choose which of these sample you are willing to provide. If you decide you don't want us to collect any samples, this is

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fine. You can talk to your Research Midwife and we will make sure that this doesn't happen. The samples will only be collected once the midwife has made sure that your baby is safe and healthy. The samples are easy to collect and won't upset your baby.

If you agree, we will ask you to collect some of your breast milk (surplus to feeding needs) and poo from your baby at the following times after your baby is born:

- Breast milk: 7 days, 30 days and 3 months.
- Poo from your baby: 7 days, 30 days, 1 year and 2 years.

If you decide to provide these samples you will be given the sample kits you will need and easy to follow collection instructions at your second visit to the research centre during pregnancy. Around the time the samples are to be collected, we will also send you a short online form to complete. The form is so that you can tell us things like when (date and time) your and your baby's samples were collected, if you are taking any medications and how you are currently feeding your baby. Once the samples are collected, we will then work with you to arrange a convenient way to return them to us. This may be by post, home collection or via drop-off locations. If you should need some help with any part of the sample collection process, completing the online form or returning the samples to us our Clinical Research team will be able to support you. As a thank you, we will give you a £10 voucher for each breast milk and each poo sample you collect and return. For more detailed information about these samples and how they will be used, please refer to our Supplementary Participant Information: Microbiome.

What will happen to the samples?

Some of your breast milk and your baby's poo samples will be sent to specialised laboratories to learn more about the bacteria that live in the gut and the nutrients in milk. Did you know...our gut bacteria and what we eat and drink play an important role in how the brain develops, and this can have a long-lasting impact on a person's mental health. We will also store some of your breast milk and your baby's poo samples in the University of Liverpool along with the other samples collected for the C-GULL Study.

The samples that you and your baby give to the C-GULL Study, are considered as donations or 'gifts'. You can still ask for them to be destroyed if you decide to withdraw from the study.

In general, there will be no tests performed on your blood, urine, hair, placenta and cord blood samples immediately. They will be stored so they are available for future research studies, some of which may not take place for many years to allow the C-GULL Study to benefit future science. 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). Over the coming years, a wide range of tests may be carried out on your samples. These tests will be approved by an ethics committee and scientifically reviewed to make sure that the research is of high quality.

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:

- tests are not done on all of the samples immediately - so it may be a long time (years) before some of your samples are tested.
- research studies may use new or experimental tests that are not yet used widely by doctors for their patients - this means that we do not yet understand what results might be expected in the general population and their meaning in terms of future health.

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Will any genetic tests be carried out?

Yes, it is likely that genetic tests will be carried out on your DNA and / or RNA and your baby's DNA and / or RNA. Did you know...by looking at genes important discoveries can be made about how some conditions such as asthma, autism or obesity develop. These genetic tests will be used for research purposes only. The results will not be given to you, your doctors or anyone else, and personal information from questionnaires and genetic information will be kept confidential.

Do I have to donate samples?

No, sample collection for the C-GULL Study is optional. You can still participate in the study without donating samples or you can select to donate some sample types and not others.

Can I change my mind?

If you decide that you no longer want us to use samples from you or your baby then you can contact us and request this. You do not need to give a reason. We will continue using your samples until you tell us that you wish to withdraw your consent. You can still participate in the C-GULL Study if you decide you no longer want to give samples.

Where can I find further information?

If you have questions or want to know more about what will happen if you decide to take part in the study, please talk to the C-GULL Research team at Liverpool Women's Hospital. Please contact us on cgullstudy@liverpool.ac.uk or 0151 795 6700. You can also visit our website 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.