Participant Information Sheet

Children Growing Up in Liverpool Longitudinal Birth Cohort

As you are having your pregnancy care at Liverpool Women's Hospital you have been included in a research study. It is important for you to understand why the research is being carried out and what it will involve. Please take time to read this information carefully and discuss it with others if you wish. A member of our research team can also go through this information sheet with you and answer any questions you may have.

Thank you for reading this.

Why are we doing the study?

Children Growing Up in Liverpool (C-GULL) is an exciting 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 early experiences in 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.

One of the main areas of focus of the study is mental health. 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. There is also evidence suggesting that the bacteria in our gut can play an important role in brain development and mental health. We will be collecting samples such as breast milk and stool (poo) from mothers/birthing parents and babies to find out more about how these things are linked.

Who will take part?

We want to involve families from different ethnic, cultural, social and family backgrounds so that we can understand how to improve the health and wellbeing of all children in the Liverpool City Region.

If you are aged 16 or older and have booked your pregnancy care at Liverpool Women's Hospital (LWH), you will automatically be included in the C-GULL Study. This is part of LWH's approach to making research apart of routine care and an option for all and follows NHS England guidance.

Being part of the study is completely up to you. If you decide that you do not want to be involved, that is absolutely fine – you can opt out at any time. Choosing not to take part will not affect the care you or your baby receive in any way.

Do I have to take part?

No, you do not have to take part – even if you agree now, you can choose to stop at any time.
The C-GULL Study uses an opt-out approach, which means that if you are receiving pregnancy care at LWH, you will automatically be included in the study unless you 'opt out' by telling us that you do not want to take part. You can do this by informing a member of your clinical care team or contacting the C-GULL research team directly on cgullstudy@liverpool.ac.uk or 0151 795 6700.

What does being part of the C-GULL Study mean?

To take part in the C-GULL Study you will need to be happy for us to 1) access your and your baby's routine NHS data (past and future) held at the hospital or through national systems (like maternity and child health records), 2) contact you about future C-GULL research and 3) securely include your data on the C-GULL research platform. You do not need

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to do anything other than this, however you can choose to help strengthen the C-GULL Study further by taking part in the other aspects of the study. A member of the C-GULL research team will contact you to discuss these further – you can be involved in as much or as little as you like. You will be asked to provide written consent for these parts of the study.

You can:

- **Answer some questions.** Twice during pregnancy (once in early and once in late pregnancy), and when your baby is 3 months, 12 months and 24 months old we will ask you to complete some questionnaires about things like your and your baby's health, wellbeing and lifestyle.
- **Provide some samples.** During your pregnancy we will ask you to give a sample of blood, urine, hair and poo. Around the time of birth, we will ask you to donate some samples, including your placenta (afterbirth), some blood left in the umbilical cord (cord blood) and a small amount of colostrum (early breast milk). Please be reassured, taking blood from the umbilical cord will not cause any pain or distress to your baby. After your baby is born, we will ask you to collect some samples of your breast milk and your baby's poo. You do not have to give all of these samples – you can choose which you are happy to provide. For more detailed information about the samples we will be collecting and how they will be used, please refer to our Supplementary Participant Information: Taking Part in the Study / Microbiome

  Shortly after birth, we will also ask if we can measure your baby's body composition (the amount of fat, bone, water, and muscle in the body) using a piece of equipment called a 'PEA POD'. Your baby will need to lie in a special incubator for a short time whilst measurements are being taken, however this should not cause any pain or discomfort. For more detailed information about the PEA POD and what will happen to your baby, please refer to our Supplementary Participant Information: PEA POD.
- **Visit one of our community centres** when your baby is two years old so that we can see how they are growing and developing. You will also be able to ask any questions you may have about your health or your baby's health and development.
- **Agree to be contacted again in the future.** We will contact you again in the future to invite you and your baby to take part in follow-up assessments (answer more questions and / or attend more visits). It is your choice whether to take part in each of these. You will be provided with full information for each and given time to decide if you would like to be involved. If you decide not to take part, the care you or your family receive will not be affected in any way.
- **Give permission for us to request additional information** that the NHS, government departments and other organisations already hold about you and your baby. We would like to look at this information so that we can understand how health and other life events are related.

For more detailed information about what will happen during the study, please refer to our Supplementary Participant Information: Taking Part in the Study or you can contact a member of the C-GULL research team.

Will my partner be invited to take part?

Yes, we will ask your permission to contact your partner (if applicable) about taking part in the study. If they agree, we will provide a link to our website where they can find more information. They will be able to register their interest online and shortly after, they will be able to consent and fill in the study questionnaires via our online systems. If they prefer to do this face to face, we can arrange for this also. Partners will also be asked if they would like to provide a blood or saliva sample. If they agree, we will arrange for them to come into the Research Centre where blood can be drawn, or a saliva sample collected by a member of our Research Midwife team. If preferred however, they can take the saliva sample themselves using a home collection kit. If your partner does not wish to take part in the study, that is completely fine. For more detailed information about partners taking part in the study, please refer to our Partner Information Sheet.

Will my taking part in this study be kept confidential?

Yes, we will follow ethical and legal guidance, and all information collected about you and your baby will be kept confidential and secure. Any personal information you give us will only be used by the research team during the course of the study. All samples and data will be coded (given a unique identification number) and stored separately from your personal details (name, date of birth, contact details etc.) to protect your identity. Only members of the research team who need to contact you will know your name and contact details. To prevent unauthorised access to your personal details we will use things like encryption, password protected computers systems, key card controlled rooms and lockable storage cabinets to make sure your information is stored securely.

How will you use my data?

We will need to use information from you and from your and your baby's medical records for this study. This information will include identifiable data, such as name, initials, date of birth, NHS number and contact details (telephone number, email address, house address and postcode). People will use this information to do the research or check your records to make sure that the research is being done properly. We will keep any identifiable data collected for at least 10 years after the study has finished.

In addition to identifiable data, the C-GULL Study will also collect demographic, health (hospital, GP, midwife / health visitor community), lifestyle, nutrition, housing, education, employment, social care and economic (income) information. A lot of this information will be obtained from the questions you will answer / questionnaires you will complete (self-reported data). However, we would also like to access health, education, social care, and economic information that the NHS and government departments (Education, Health and Social Care, Work and Pensions) already hold about you and your baby. This is called linked data, and we would only do this with your permission. To take part in the C-GULL Study you will need to agree to us accessing information from your and your baby's health records, but anything more than this will be optional.

Data linkage in a longitudinal study such as the C-GULL Study means collecting information from different sources and using it to track the health and development of a person throughout their life. To link all this information together, identifiable information like their name and date of birth is used. This helps researchers to identify patterns in the data and understand what factors might contribute to them. Data linkage in a longitudinal study usually starts from when the person was born.

To ensure that your data is handled with the utmost care and respect, the C-GULL Study will only use your identifiable information as part of the data linkage process once you have agreed to take part in the study. By doing so, we can help protect your privacy and ensure that your data is handled securely.

Dynamic consent is a process that enables individuals to have control over their involvement in research studies. In the C-GULL Study, we would like to stay in touch with you after your child reaches the age of two years to obtain your consent for continued involvement in the study. This means that you can choose to opt out of any further data collection or analysis if you prefer. We believe that by using dynamic consent, we can establish a dialogue with you and ensure that you are informed about the study's progress and how your data is being used. This approach allows us to maintain transparency and trust with our participants and respects their privacy.

In line with the C-GULL Study opt-out model, your personal and health information will be used for research purposes as part of the study unless you choose to opt out. This includes securely linking to routine NHS and government data to understand long-term health and development. You can opt out at any time, and we will honour your preferences regarding what data can be accessed or used.

You can find out more about how we use your information

- from the leaflet available at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to legalservices@liverpool.ac.uk, or
- by ringing us on 0151 795 0523.

For more detailed information about the data we are collecting and how it will be used, please refer to our Supplementary Participant Information: Data.

What are the possible benefits of taking part?

Taking part in the C-GULL Study will allow the development of your child to be tracked throughout their childhood and teenage years, to adulthood and beyond. The samples and data collected from you and your child will allow us to better understand the factors that can improve the lives and health outcomes of the children (and their families) within our city.

What are the possible risks of taking part?

The risks involved in the study have been carefully assessed and the main objective of the research team is to maintain your and your baby's safety at all times. Taking part in the study will not put you or your baby at any risk of harm. The samples collected have been used with pregnant women/people before and are not known to have any risks. The questions / questionnaires you will be asked to answer should not make you feel uncomfortable, and you can decide whether to answer them or not. However, if you should experience any discomfort at any time during the study, please tell a member of the research team immediately. If the team member has any serious concerns about your health, wellbeing or safety, they will ensure that the appropriate support is provided to you via the Liverpool Women's NHS Foundation Trust safeguarding pathway. There are also contact details provided at the end of this information sheet for organisations who can offer support should you need it.

What will happen if I do not want to continue in the study?

You are free to withdraw at any time throughout the course of the study, without explanation. The care you or your family receives will not be affected in any way. If you withdraw, you can ask the C-GULL Study for:

- **No further contact:** we would not contact you again but would have your permission to keep and use information and samples that you have already given and to request further information from your health and other records in the future.
- **No further access:** we would not contact you again and would not request information from your health and other records in the future. We would still however have your permission to keep and use the information and samples you have already given us.
- **No further use:** we would no longer contact you and would not request information from your health and other records in the future AND any information and samples already collected would no longer be given to researchers.

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Can I take a break from the study?

Yes, if you feel you need a break you can opt out for a while. During this period we will not contact you but would have your permission to continue to collect information from your health and other records. Once the break is over, we will get back in touch to check that you are happy to take part in the study again.

What will happen to any samples I give?

Sample collection for the C-GULL Study is optional. You can choose which samples you would and would not like to give. Any samples you do give will be collected specifically for the study. For most of the samples you provide, there will be no tests performed immediately. They will be stored so that in the future researchers will be able to use them to better understand the link between early-life and later poor health. We will use some of the breast milk and poo samples you and your baby provide straight away. We will use these samples to look at the bacteria that live in the gut and the nutrients in milk to find out more about the role they play in brain development and mental health.

All samples will be coded and stored separately to any personal details (name, date of birth, contact details etc.) you provide to us. We will make sure your samples are handled properly and ethically and stored securely throughout the course of the study.

If you agree, your samples will be used by approved researchers in specialised laboratories in the UK and laboratories abroad with specific ethical approval in place. As a result, some of your samples and data may be transferred out of the UK. We will ensure that they are sent in a fully anonymised format so that you and your baby can not be identified.

If you give permission, we will extract your DNA and / or your RNA from some of your samples for use in human genetic studies. If you agree to gift (donate) your samples, they will be used in other ethically approved research in the future.

For more detailed information about the samples we are collecting and how they will be used, please refer to our Supplementary Participant Information: Taking Part in the Study / Microbiome.

What will happen to the results of the research study?

It is intended that the results generated from the study will be published as research papers in medical journals. We will also engage with national and charitable organisations. Summaries of the study results will also be made available on our website and social media.

Where can I get further information or discuss any problems?

If you have any questions or concerns about any aspect of this study, please contact a member of the C-GULL Study research team on 0151 795 6700. If your concerns are not resolved, you can contact the Patient Advisory Liaison Services (PALS) on 0151 702 4353. You can also visit PALS by asking at the Liverpool Women's Hospital main reception.

Who is organising and funding the research?

Wellcome Trust is funding the study (Reference: 217067/Z/19/Z) and Professor Louise Kenny is the study Chief Investigator. The study is sponsored by The University of Liverpool and managed by the Harris Research Centre, University of Liverpool.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed for ethical considerations and given a favorable opinion by members of the North East - Newcastle and North Tyneside 1 Research Ethics Committee.

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Where can I find further information?

Should you need any further information about the study, please contact us on cgullstudy@liverpool.ac.uk or 0151 795 6700. You can also visit our website cgullstudy.com or follow us on social media @ChildrenGrowing.

A member of the C-GULL research team will contact you to discuss all the aspects of the C-GULL Study (questionnaires, samples, face-to-face assessments, data linkage etc) however you can also find further information about these and consent to take part in as much or as little as you want by visiting our website using the link above or the QR code below.

Organisations who offer support should you need it:

- Mersey Care (urgent mental health support): https://www.merseycare.nhs.uk/urgent-help
- Anxiety UK: https://www.anxietyuk.org.uk/anxiety-type/stress/
- Merseyside Domestic Violence Service: https://www.mdvs.org/
- Pandas (postnatal depression support): https://pandasfoundation.org.uk/
- Bambis (breastfeeding support): https://www.liverpoolbambis.co.uk

Thank you for taking the time to read and consider this information sheet. Should you decide to take part in the study, you will be given a copy of the information sheet and a signed consent form to keep.