

Father / Partner / Care Giver Information Sheet

Children Growing Up in Liverpool Longitudinal Birth Cohort

We are inviting pregnant women/people and their partners to take part in a research study. Before you decide whether or not to take part it is important for you to understand why the research 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 go through this information sheet with you and answer any questions you may have. Please take time to decide whether or not you wish to take part.

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 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 have I been asked to take part?

We are inviting you to take part because your partner is pregnant and is planning for their care to be at Liverpool Women's NHS Foundation Trust. Your partner may have been having appointments at the hospital. Midwives in these clinics are telling pregnant women/people and their partners, like you, about the C-GULL Study and inviting them to take part.

Do I have to take part?

No, you do not have to take part. You can choose whether to take part or not. Even if you agree now, you can choose to stop at any time. If you decide not to take part, you and your partner's healthcare will not be affected.

What should I do if I want to take part?

If you would like to take part in the C-GULL study you can register your interest online and a member of the research team will contact you to make an appointment for you come to the research centre at Liverpool Women's Hospital or one of our community centres. You can arrange this appointment at a time that is convenient for you. At your appointment, a member of the team will talk to you about the study, answer any questions you may have and ask you if you would like to take part. You can take as much time as you need to decide. If you are happy to take part in the study, you will need to complete and sign the study consent form. The research team will be available to support you with this process, if needed.

What will happen to me if I take part?

If you agree to take part in the C-GULL Study, we will ask you to:

- **Visit the research centre at Liverpool Women's Hospital or one of our community centres.** We will ask you to visit us once during your partner's pregnancy. This can be when your partner is attending for one of their pregnancy visits or at another time that is convenient for you. At the visit you will be asked to provide some information about yourself, give a small amount of blood or saliva and answer some questions. If you have

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limited time or would simply prefer it, we can send the questions to you by email to complete at home in your own time.

- **Agree to be contacted again in the future.** We may wish to contact you 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.
- **Give permission for us to request information** that the NHS, government departments and other organisations already hold about you. We would like to look at this information so that we can understand how health and other life events are related. This will only be done with your permission. You will need to agree to us getting some information from your NHS and healthcare records, but anything more than this will be optional.

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

Will my taking part in this study be kept confidential?

Yes, we will follow ethical and legal guidance and all information collected about you 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 your 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). 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), 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. This is called linked data and we would only do this with your permission.

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.

To ensure that your data is handled with the utmost care and respect, the C-GULL Study starts data linkage from the point of your consent. This means that your NHS number and date of birth will only be used to link information collected after you have agreed to participate 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

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or analysis if you prefer. We believe that by using dynamic consent, we can establish a dialogue with you and ensure that you're 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.

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- 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 followed throughout their childhood and teenage years, to adulthood and beyond. The research supported by the samples and data collected by the C-GULL Study from all those who take part 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 safety at all times. Taking part in the C-GULL Study will not put you at any risk of harm. The samples collected have been used before and are not known to have any risks. Many of the questions you will be asked have been asked in other similar studies. They should not make you feel uncomfortable and you can decide whether to answer them or not.

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 anyway. 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 the information and sample 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 sample 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 the information and sample you have already given would no longer be provided to researchers.

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.

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What will happen to any samples I give?

Sample collection for the C-GULL Study is optional. If you decide not to give a blood or saliva sample you can still take part. If you do provide a sample, it will be collected specifically for the study. In general, there will be no tests performed on your sample immediately. It will be stored so that in the future researchers will be able to look into the link between early-life and later poor health to better understand the factors that can improve the lives and health outcomes of the children (and their families) within our city.

Your sample 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 sample is handled properly and ethically and stored securely throughout the course of the study. Samples will be stored in a facility licensed under the Human Tissue act 2004 (England and Wales).

With your permission, we will use your sample to extract your DNA and / or RNA for use in human genetic tests. 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.

If you agree, your sample 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 sample and data may be transferred out of the UK. We will ensure that they are sent in a fully anonymised format so that you cannot be identified.

If you agree to gift (donate) any of your stored sample, it will be used in other ethically approved research in the future.

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.

You can register your interest in the study by visiting our website using the link above or the QR code below, and completing the registration form within the 'Taking Part' section.



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.