Process Evaluation Information Sheet

What is the purpose of the evaluation?

Clinical trials can be difficult to conduct and many experience problems with recruitment or delivering the study as intended. This can lead to increased cost or trials being stopped early. During the first 12 months of The neoGASTRIC study we will be inviting both parents and staff involved in the trial to share their experiences with us to help improve the trial going forward. Importantly, we will use the findings of this evaluation to inform staff training and provide information how we can run the trial better to make it family centred. This hospital is one of four hospitals taking part in the process evaluation, which is being led by the University of Liverpool.

What is involved?

We would like to invite you to complete a brief questionnaire either on paper (please ask a nurse or doctor) or by using this link: link to be inserted. The questionnaire will ask your views about the trial and your reasons for staying involved or not opting out. It will also ask questions about what informed these decisions and anything we can do better when we approach parents about The neoGASTRIC study in the future.

As part of the process evaluation study, a researcher from the University of Liverpool would also like to talk to some parents by telephone. These discussions will last between 30 - 60 minutes and will include similar questions to the questionnaire but in more detail, such as how you felt about your baby's involvement in The neoGASTRIC study and the consent process. This is separate from your decision about your baby's involvement in The neoGASTRIC study. We are inviting all parents and legal representatives to take part **including those who opt-out of The neoGASTRIC study**. It is important to find out why parents do and do not opt out of to improve how we run the clinical trial. Both parents can take part in the questionnaire and/or the interview (if applicable).

Do we have to take part?

Taking part is completely voluntary. If you decide not to take part you do not have to give a reason and your baby's care will not be affected in any way.

What do I do if I would like to take part in the process evaluation?

Please let us know if you would like to participate in any part of the process evaluation by initialling the relevant boxes on the consent section at the top of the questionnaire. Please provide your contact details in the consent section at the end of the questionnaire if you would also like to take part in an interview. Please return these to the person who spoke to you about the research. A researcher from The University of Liverpool will get in touch with you to arrange the interview at a convenient time within the next month. Interviews will be conducted online or via telephone (whichever you prefer). All information collected will be kept confidential and held securely.

Interviews will be professionally transcribed by a company called UK Transcription. If you have any questions about the process evaluation please contact: Dr Kerry Woolfall Email: ***k.woolfall@liverpool.ac.uk***.

After the interview, we will send you a £30 Amazon voucher to thank you for your time.

Are there any risks in taking part?

This is a low risk study. The majority of questions will be about the clinical trial. However, at the beginning of the interview we will be inviting you to discuss your experiences of being in hospital with your baby. Such personal questions about your child's experience may be upsetting for some. If you would rather not answer such questions, please let the interviewer know. You can decide not to answer a question at any time. The interview can also be paused or stopped at any time you wish.

How will my data be used and what happens if I want to stop taking part?

We will need to use information from you for this research project. This information will include your name and contact details. We will keep all information about you safe and secure. The University of Liverpool will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. You can stop being part of the study at any time, without giving a reason.. If you change your mind after the data has been anonymised we will keep anonymised information about you that we already have because some research using your data may have already taken place and this cannot be undone.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

People within Imperial College London and their study team will use this information to do the research or to check your records to make sure that the research is being done properly and the information held (such as contact details) is accurate. Only the research team, the study organisers in Oxford and people from the sponsor or regulatory authorities (who check on studies like this) will see your data.

Imperial College London is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for 25 years after the study has completed in relation to primary research data. The process evaluation aspect of the study is expected to finish in 2023 or 2024.

Dr Kerry Woolfall, University of Liverpool acts as the Data Processor for this study.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

For more information / confirmation regarding the end date please contact the study team, see **'Where can you find out more about how your information is used' for contact information**.

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

- Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London rely/relies on "scientific or historical research purposes or statistical purposes.

International transfers

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK

adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

Other Imperial College London employees include staff involved directly with the research study or as part of certain secondary activities (which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

Potential use of study data for future research

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the ***UK Policy Framework for Health and Social Care Research***.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

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Where you can find out more about how your information is used?

You can find out more about how we use your information

- at ***www.hra.nhs.uk/information-about-patients/***
- by asking one of the research team
- by sending an email to ***neogastric@npeu.ox.ac.uk***
- by ringing us on ***(0)1865 617927***
- or by going to ***www.npeu.ox.ac.uk/neogastric***

What happens if I have a complaint?

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to ***k.woolfall@liverpool.ac.uk*** or by ringing us on 0151 794 4634

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at ***dpo@imperial.ac.uk***, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) - via ***www.ico.org.uk***. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (see details below). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

Who is organising and funding the research?

The National Perinatal Epidemiology Unit, Clinical Trials Unit (NPEU CTU) at the University of Oxford, UK in partnership with Monash University, Australia are coordinating and managing The neoGASTRIC study on behalf of the sponsor, Imperial College London. This process evaluation part of the study is being led by the University of Liverpool.

The neoGASTRIC study is funded by the National Institute for Health and Care Research in the UK and National Health and Medical Research Council in Australia. The doctors and nurses conducting the research are not receiving payment or benefits over and above their normal salary.

Who has reviewed the study?

The study has been reviewed by the London-Riverside Research Ethics committee (Ref: 23/LO/0060) who have agreed that the study is being conducted in a correct and appropriate manner. Thank you for your time. We are very grateful that you are considering taking part in this study.

Contact for further information or if you have any concerns:

Principal Investigator:	**Chief Investigator:**	**Patient Advisory Liaison Service (PALS):**
{_LEAD_}	Professor Chris Gale Imperial College London 0203 315 3519 christopher.gale@imperial.ac.uk	{_PALS_}

Thank you for reading this leaflet – please discuss this study with the doctor or nurse who is looking after your baby if you have any questions.

neoGASTRIC Study Team

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www.npeu.ox.ac.uk/neogastric

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