The 22 Week Study

# Clinical Management and Short-Term Outcomes of Neonates Born at 22 Weeks in UK Neonatal Intensive Care Units (The 22 Week Study)

IRAS ID: 346626

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Dear Parent(s),

Thank you for reading this leaflet. It explains how information about your baby that is routinely recorded in the medical notes is being used in a study of babies born at 22 weeks in the UK.

## Background

In the UK, most babies born at 22 weeks' gestation have only been offered stabilisation and admission to a neonatal unit since 2019. Only a small number of babies are born this early each year and sadly most of them do not survive for very long or until going home. This means that we don't have a lot of information about these babies, the intensive care support given or outcomes in the UK. All babies have clinical information recorded about them in their notes. This helps the healthcare team communicate with each other and record what happens during a baby's time in hospital.

## Why we are doing the study and how it will be done

Your baby has been included in this study because they were born at between 22+0 and 22+6 weeks of pregnancy and are/have been in a hospital with a neonatal unit that can provide intensive care during the timeframe of the study. Selected members of the team looking after your baby will be collecting some of this clinical information on a secure computer system (database), about the care given to your baby such as stabilisation (or resuscitation), breathing machine settings, feeding, treatments and test results. This will occur from when they are born and will finish when their neonatal journey ends, whether they are discharged home, remain in hospital at 44 weeks corrected gestational age or if they die. We intend to combine the data for all babies across the UK and then analyse it.

This will **not** change the care that your baby receives (or received) – it is entirely observational.

The anticipated benefit of collecting and analysing this information will be to help healthcare professionals provide useful information to families about what to expect in the future and to help us better understand and address some of the challenges faced by 22-week babies. The potential risk in the study is the possibility of your baby's information being lost or identified.

## Data Protection

Imperial College London (University) 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.

We will only collect information that we need for the study. All the information collected will be under a unique study number and there will be **no** personal details like name, date of birth or hospital number included. We will follow all privacy laws and legislation that are relevant to the specifics of the 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. We will keep your study data for a maximum of 10 years, then it will be securely archived or destroyed.

The data may be combined or linked with other routinely collected data that has already been used on a population level, which you can find out more about here: https://www.imperial.ac.uk/neonatal-data-analysis-unit/neonatal-data-analysis-unit/information-for-patientscarers/

**Consent and Registration**

You are **not** required to give consent. The study has been appropriately registered, received a favourable opinion from REC (25/PR/0089) and been reviewed in line with data-processing laws. The results of the study will be available via publication in a scientific journal, conference presentations and at www.neotrips.org after completion and analysis, which may take several years after the end of the data collection period (up to September 2026 approximately).

**International transfers**

Your data will not be shared outside the UK.

**Legal basis**

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 relies on scientific or historical research purposes or statistical purposes.

**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 (including 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

**What are your choices about how your information is used?**

- You can stop your baby being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- if you have any questions, please ask the team looking after you/your baby or contact the research team via info@neotrips.org
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

We need to manage your records in specific ways for the research to be reliable. This means that we may not 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. 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.

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

You can find out more about how we use your information using the following methods:
Our leaflet which can be found here: www.hra.nhs.uk/patientdataandresearch
You can ask one of the clinical team involved in the study or email h.mcdermott@imperial.ac.uk
You can also 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.