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neoWONDER

Imperial College London

Participant Information Sheet For Survey

Imperial College Research Ethics Committee Approval ID number: REC 20/YH/0330

Title of Study: "Parent and patient perspectives on linking existing data to evaluate long-term health and wellbeing of preterm babies"

Contact Details of the Principal Researcher: Dr Cheryl Battersby c.battersby@imperial.ac.uk

Contact Details of researcher: Dr Mary Sawtell m.sawtell@ucl.ac.uk

1. Invitation

You are invited to complete a survey seeking your views on data linkage and long-term outcomes in preterm babies. We are a group of neonatologists, researchers, parents and ex-patients who want to ensure preterm babies lead healthy and fulfilling lives as they grow up into children and adults. This survey thas been developed with parents and ex-patients to find out your views on data linkage and long-term outcomes in preterm babies.

In agreeing to participate in this survey, you are voluntarily taking part in a research project. Before you decide, it is important for you to understand why the research is being done and what participation will involve. Please take time to read the following information carefully and make sure you understand it.

2. What is the purpose of the survey?

The research aims to obtain the views of patients and members of the public with experience of preterm birth about data linkage and long-term outcomes . This includes: the importance of long-term outcomes; whether data linkage using personal identifiers is acceptable; ways to raise awareness; practicalities of disseminating information and opportunities for opt-out (if desired); and ways to facilitate data linkage going forwards. Participants will also be able to indicate their interest in a follow-up one-to-one interview at the end of the survey.

This survey is part of a research programme called neoWONDER which aims to link together health, education and other data routinely collected for children born preterm. This linkage of data will allow us to understand how the care a baby receives in the early months of their life affects their health and learning as they grow up i.e. their longer term health and education outcomes. Once we know this, we can begin to understand whether and how things can be done differently in neonatal units to improve longer term outcomes.

3. Why have I been chosen?

You have been invited because you have experience of preterm birth. You are a parent or carer of a preterm baby or an adult born preterm.

4. Do I have to take part?

It is up to you to decide whether or not to take part. You can withdraw at any time without submitting your responses.

5. What will happen to me if I take part?

You will be invited to read the information sheet that explains the purpose of the survey. If at this point you have any questions Cheryl Battersby (c.battersby@imperial.ac.uk) will be happy to discuss

the study with you and answer any questions you may have. If you are still happy to take part, you will begin the survey following completion of the on-line consent questions. The online survey will be administered through Qualtrics software supported by Imperial College London will take approximately 15 minutes to complete.

The questions are related to data linkage and long-term outcomes for babies born preterm. Once the survey is complete there will be no further expectations for involvement or requests for information.

6. What are the possible disadvantages or risks of taking part?

We would like to inform you of the possibility for slight distress when answering the survey questions if they are sensitive and/or upsetting to you.

7. What are the possible benefits of taking part?

You might find that answering the questions increases your awareness of the use of data recorded about you or your child. There are wider possible benefits of taking part; your response will be used in research that aims to improve the long-term outcomes of children born preterm.

If you also consent to be re-contacted about potential involvement in follow-up 1 to 1 interviews or future studies, you are agreeing to subsequent contact but are in no way obliged to participate in follow- up research or future studies. You may decide whether to participate at the point of contact, if we do contact you.

8. What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. 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 *(Cheryl Battersby c.battersby@imperial.ac.uk)*. The normal National Health Service complaint 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."

9. How will we use information about you?

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 properly. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from you and your medical records for this research project. This information will include name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

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.

LEGAL BASIS

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.

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

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). 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 European Commission (**EC**) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

Other College employees, 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 being part of the study at any time, without giving a reason, but we will keep information about you that we already have. 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 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. We will keep the samples you have given to provide other reference ranges for pregnancy.

WHERE CAN YOU 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 c.battersby@imperial.ac.uk, or
- by ringing us on 020 3315 3047
- Link to Research website - https://www.neowonder.org.uk/

COMPLAINT

If you wish to raise a complaint on how we have handled your personal data, 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 are not satisfied 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). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

10. What will happen to the results of the research study?

The survey and interview responses will be analysed and used in an application to the Confidential Advisory Group (CAG) seeking permission to link together existing health and education data for around 90,000 preterm babies born since 2007 in England and Wales. The CAG is an independent body that protects and promotes the interests of the patients and the public, whilst facilitating appropriate use of patient data beyond direct patient care. You can read more about the CAG here and more about the neoWONDER study here.

We will analyse these for the purposes of the neoWONDER study only; no other use will be made of it without your written permission, and no one outside the project will be allowed access to your responses. All responses will be processed in a pseudo- anonymised form (personally identifiable information will be removed). Data will be stored so long as it is required for the research project. Any written and published information from the study will be in aggregated form with no possibility of identifying the study participants.

11. Who is organising and funding the research?

The study is being led by Dr Cheryl Battersby and researchers at Imperial College London. Funding has been provided through a fellowship awarded to Dr Battersby by the National Institute for Health Research.

12. Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by Yorkshire & The Humber -Leeds East Research Ethics Committee (Ref 20/YH/0330).

13. Contact for Further Information

Name: Dr Cheryl Battersby

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Email (if applicable): c.battersby@imperial.ac.uk

Thank you for reading this information and for considering to take part in this research study. Should you have any questions, please contact one of the researchers