Parent Information Sheet and Consent Form

Invitation to MRI scanning

FULL STUDY TITLE: **Respiratory Health Outcomes in Neonates** (RHiNO)
CHIEF INVESTIGATOR: **Professor Sailesh Kotecha** (University Hospital of Wales, Heath Park, Cardiff)

What is the purpose of the study?

A new MRI scanning technique has been developed by Sheffield University which is radiation free and can detect the structure of the lungs in far more detail than previously.
We would like to use this technique for children born prematurely (who do and do not have breathing symptoms) and compare the results to those who are born on time.

Why has my child been chosen?

You and your child have been asked to take part in this study because he/she was born on time and had normal breathing tests.

Does my child have to take part?

No, taking part is completely voluntary. It is up to you and your child to decide whether or not to take part. Even if you do agree to join, you can stop at any time without giving a reason.
A decision to leave the study, or a decision not to take part, will not change the standard of care you and your child receive now or in the future.
If you do take part, you will be given this information sheet to keep and be asked to sign a consent form.

What will happen to my child if we agree to take part and how long will it take?

We would like you to attend the University of Sheffield Radiology Unit, based at the Royal Hallamshire Hospital, who have the specialised equipment and expertise we need to perform the MRI scans. We will pay for travel, food, entertainment and accommodation (if you wish to stay overnight) for you and your child. You may be offered the opportunity to travel together with other families who have agreed to take part.

When you arrive, you will be given a leaflet explaining how the scan will work. Before the scan, the team will ask your child to do a blowing test, which involves a few minutes of normal, regular breathing. The MRI scan is painless but does make some noise. MRI scans involve lying in a relatively narrow tube whilst the scans are performed, and this takes about 1 hour. Although well tolerated by most patients, some children may be uncomfortable with this.
If your child has a history of claustrophobia (fear of enclosed spaces) or if you think that they will find this process uncomfortable or upsetting, please let a member of the team know so that we can discuss this in more detail. Your child will be asked to breathe in a small volume of Helium gas and hold their breath for a few seconds before the scan. Helium is a harmless, colourless and tasteless and helps us see the airways.

What does my child have to do if we agree to take part?

If you and your child decide to take part in this study it is important that you both follow the instructions and advice given to you by the study team. If you are unsure about anything, please ask us. Before taking part and throughout the study it is important that you tell the study doctor/nurse (or any of the team) about any changes in your child's health that you have noticed.

What are the other possible disadvantages and risks of taking part?

The MRI scan is painless and radiation-free. Anyone with a metal implant or cardiac pacemaker should not have an MRI scan.

What are the possible benefits of taking part?

We are conducting this research so that we can understand why some children born prematurely continue to have breathing problems and symptoms. As such, this will not help your child personally. The information we get might help to improve the treatment of children born early who do have symptoms in the future.

What happens when the research study stops?

We will collect all the information together and compare the results between those born prematurely or on time to see if there are any differences. This may help us know why children born prematurely continue to have breathing problems.

What will happen if my child or I don't want to carry on with the research?

You or your child can withdraw at any time, if you wish. All data collected up until the time of withdrawal will be anonymised (this means that a number will be used instead of your child's name so that no-one will know the information is about them) and included in the study analysis, unless you specifically state otherwise.

What if there is a problem?

If you have any questions about the study, please contact Professor Sailesh Kotecha or Dr Michael Cousins. If you are still unhappy after you have spoken to them and wish to complain formally, you can do this through the NHS Complaints Procedure.

In the event that something goes wrong and your child is harmed during the research study, there are no special compensation arrangements. If your child is harmed due to someone's negligence then you may have grounds for a legal action. However, you may have to pay your own legal costs. The normal NHS complaints mechanism will still be available to you.

Will my child's taking part be kept confidential?

Yes. As in the first parts of the study, all of the information about your child's participation will be kept confidential. The paper files used to record information in this study will be labelled with an anonymous study number only. Giving information to someone else ('a third party') is not allowed. However, it will be necessary for authorised people from regulatory authorities, the study sponsor, or NHS bodies to check the study is being carried out correctly. Medical information may be also given to your child's doctor or appropriate medical personnel responsible for their welfare. By signing the consent form you are giving permission for this to happen. In the event of the results of the study being sent to Health Authorities or published, all of your child's records will be kept confidential and your child's name will not be disclosed to anyone outside of the study. All documents and files relating to the study will be stored confidentially for a maximum period of 25 years.

Involvement of the General Practitioner/ family doctor (GP)

With your consent, the study doctor will write to your child's GP to let them know that they are taking part in the study. The study doctor may ask your child's GP for further medical information about them if necessary.

What will happen to the results of the research study?

The results will be published in medical journals and presented at medical conferences. Your child's confidentiality will be ensured at all times and they will not be identified in any publication. At the end of the study, the results can be made available to you (should you wish). They will also be published on the RHiNO website.

Who is organising and funding the research?

The study is sponsored by Cardiff University and funded by the Medical Research Council (MRC). Cardiff University have assigned the management of study to the North Wales Organisation for Randomised Trials in Health (NWORTH) at Bangor University, and made arrangements for the MRI scans to be done by the University of Sheffield.

Who has reviewed the study?

The study was approved by the South West-Central Bristol Research Ethics Committee (Ref 15/SW/0289). It has been registered with the International Standard Randomised Controlled Trial Number ISRCTN14767962.

Contact details:

Please do not hesitate to contact the RHiNO team on telephone 029 2074 4187 or by email (rhino@cardiff.ac.uk) if you have any questions. Further information is available at our website http://rhino-health.org.

Thank you for reading this information sheet

BEBE
Born Early Breathe Easy
University Hospital of Wales, Heath Park, Cardiff CF14 4XW Tel: 029 2074 7747

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysol Caerdydd a'r Fro
Cardiff and Vale University Health Board

Parent/Guardian Consent Form

RHiNO: Respiratory Health Outcomes in Neonates (Part 3)

1 I confirm that I have read and understood the information sheet dated 'Version 3 03/08/2016' for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.	Initial:
2 I understand that my child's participation is voluntary and we are free to withdraw at any time, without giving a reason, and without my child's present or future medical care or legal rights being affected.	Initial:
3 I understand that relevant sections of any of my child's records and data collected during the study relating to my child may be looked at by responsible individuals from the sponsor, funder, regulatory authorities or hospital. I give permission for these individuals to have access to these records where it is relevant to taking part in this research.	Initial:
4 I agree that personal identifiable information will be collected, stored and used by the NWORTH to enable follow-up of my child. This is on the understanding that all information will be treated confidentially.	Initial:
5 I agree to my family doctor being informed of my child's participation in the MRI study.	Initial:
6 I agree to allow my child to take part in the RHiNO study (part 3).	Initial:

Name of Child:

Name of Parent:	Signature:	Date:
Researcher:	Signature:	Date:

Original for case notes, 1 copy for parent/guardian, 1 copy for investigator site file