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University Health Board

Children's Information Sheet

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 a research study? Why is this study being done?

A research study is what you do when you want to learn about something or find out something new. We want to find out if a new type of test, an MRI scan, can help us find out more about why some children who were born early have breathing problems. An MRI is a sort of scan that gives pictures of the lungs. We would like to compare the results of children born early (who have breathing problems or not) and those who were born on time.



Why was I asked to take part?

You were chosen to take part because we found you had normal scores on your breathing tests when you visited the laboratory. This part of the research study will involve about 100 children like you in Wales.

Did anyone else check the study is OK to do?

Before any study is allowed to happen, it has to be checked by a group of people called an Ethics Committee. The Ethics Committee is a group of experts and ordinary people who look at studies very carefully to decide whether they are OK to do. An Ethics Committee has looked at this study and decided it is OK.

Do I have to say yes?

No – not at all. It's up to you! Just say if you don't want to take part. Nobody will mind.

If you do take part, you will need to write your name on a form called an 'assent form'. This form is to say that you understand the study and what will happen if you join. You will be given your own copy of this form to keep as well as this information sheet.



Will joining in the study help me?

This study will not help you personally, but in the future the information we get from this testing might help other boys and girls with breathing problems who are born early.

Who will know that I am in the study?

The study team who are taking care of you will know. So will the doctor who usually looks after you (your GP).

What will I need to do and how long will it take?

We are asking families to make a trip to Sheffield to visit a hospital which has the right type of MRI scanner. The test is quick to do but you will have to lie down inside the scanner and keep as still as you can for a little while. Some people find the scanner noisy, but this is normal and nothing to worry about. Your family may decide to stay overnight before or after visit. If you do we will arrange a hotel for you to stay and make sure you are looked after.

How will the information about me be kept private?

Everything you tell us is private. The only time we would ever tell somebody what you have said is if something made us worried about you. All information collected for this study will be kept safely on the computer or as paper records. Of course, you can tell your family and friends about the study if you want to.

What happens when the research stops?

We will collect all the information together and we will decide if it is useful for doctors to help children who were born early.

What happens if there is a problem with the study?

If you think there are any problems with the study or if you have any worries about it you can tell your parents or carers. You can also tell the study nurse or doctor. They will do their best to answer your questions.

If you are still unhappy you can talk to someone else. Your parents or carers will probably be the best people to talk to.





What shall I do now?

Now you know about the study you need to think about whether you want to join or not.

Who can I talk to for more information?

If you have any questions at all, at any time, please contact:

The RHiNO team by

telephone (029 2074 4187)

or email (rhino@cardiff.ac.uk)

Further information is available at our website
<http://rhino-health.org>.

What if I don't want to do the study anymore?

If you want to stop the study at any time, just tell your parents or carers, study doctor or nurse. They will not be cross with you. If you say no or want to stop the study at any time it will not change the way the doctors and nurses will look after you.

What will happen to the results of the study?

We will write reports for the doctors and nurses who look after children with breathing problems. The results will also be written in special magazines (scientific journals). No-one will know that they are your results because your name will not be written on them. We will put the results on the study website so you can see them too.



Thank you for reading this information sheet.
We hope you have found the information helpful.

Children's Assent Form

RHINO: Respiratory Health Outcomes in Neonates (Part 3)

Young person (or, if unable, parent or guardian on their behalf) to circle all they agree with:

Have you read (or had read to you) the information about this study?	Yes	No
Has a doctor or nurse explained this study to you?	Yes	No
Do you understand what this study is about?	Yes	No
Have you asked all the questions you would like to?	Yes	No
Have all your questions been answered in a way you understand?	Yes	No
Do you know that it's OK to stop taking part at any time?	Yes	No
Are you happy to take part in this study?	Yes	No

If the answer to any question is 'No', or you don't want to take part, don't sign your name.

If you DO want to take part, please write your name and today's date below:

Your name:

Date:

Your parent/guardian must also write their name here too if they are happy for you to take part:

Sign:

Print:

Date:

The doctor or nurse who explained the study needs to sign as well:

Sign:

Print:

Date:

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