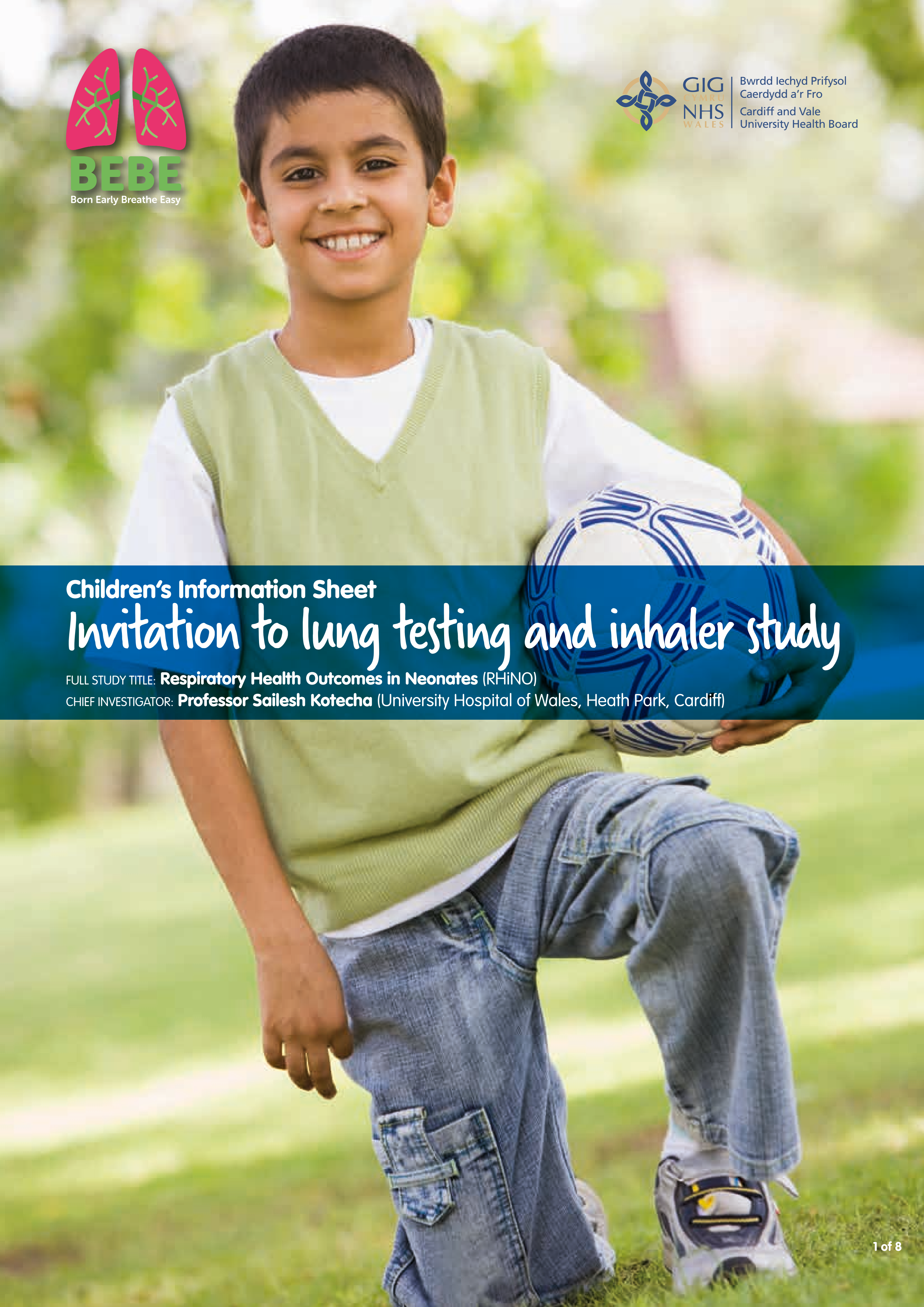

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Children's Information Sheet

Invitation to lung testing and inhaler study

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

Why was I asked to take part?

You were chosen to take part because when we visited you at home, our nurses found out that your breathing might be improved by trying a medicine. This part of the research study will involve about 200 children like you in Wales.

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. It can help doctors and nurses and other people in the hospital find out which are the best medicines to use. This research study looks at two different medicines called 'Salmeterol' and 'Fluticasone'. Both of these medicines are already used to help children with breathing problems. What we don't know for certain though, is if Salmeterol and Fluticasone help the breathing problems of children who were born early (prematurely).

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. Your Mum or Dad will also have a form to sign to say it's OK.

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

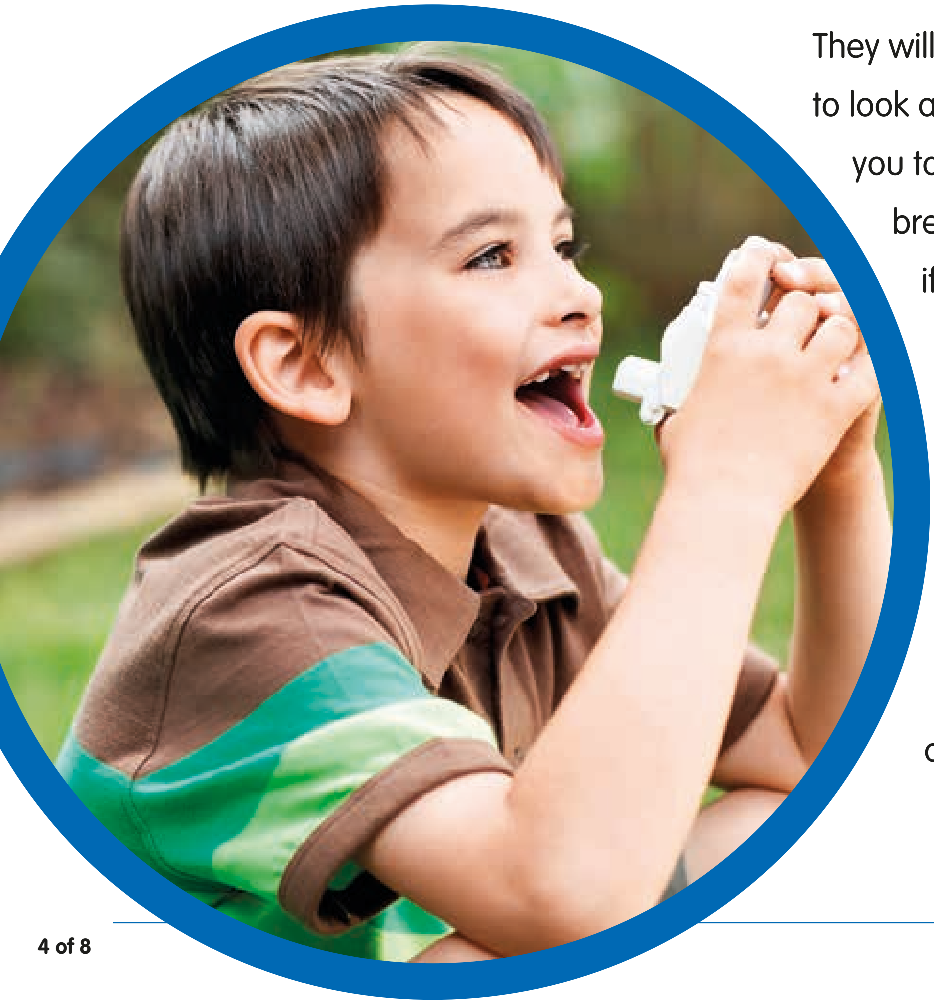
We would like to arrange for you and your parents or carers to come and see us for 2 visits. At your first visit you will see either the study doctor or nurse and they will talk to you about the research. If you say yes to joining the study, you will need to answer some questions and tell the doctor or nurse about how your breathing problems affect you (if they do). They will check you over to make sure that you are well enough to be in the study. They will also measure your growth, development, and how much muscle and fat you are made of. All of these tests need you to stand still and take just a few moments.

We would like to do an allergy 'skin prick' test. The nurse or doctor will drop small drops of liquid on your arm and gently 'prick' your skin. We do not break the skin or make it bleed, and it does not hurt. Sometimes your arm will be itchy, but this will go away quickly and the nurse or doctor will keep checking this is OK.

The doctor or nurse will also measure how much air you can breathe in and out of your lungs by asking you to do some blowing tests. For some of the tests you will need to blow the air out of your lungs in one big breath; for others you will just need to breathe quietly. Some of the tests are done while sitting inside a breathing box. For one of the tests we will ask you to peddle an exercise bike to measure how fit you are.

Last of all, the nurse or doctor will ask if you would mind us having a sample of your urine (wee). We would also like to take a sample of your saliva (spit), but only if your parents or carers think this is OK. These can be tested to help us understand more about reasons for breathing problems. You will have time to practise each test so you can do your best. All the tests might take about 3 to 4 hours, but don't worry, there will be plenty of time to take a break.

At the end of the tests, if the doctor and nurse find the same results as your blowing test at home we would like you to try taking some medicine that might help your lungs.
This is called an 'inhaler'.



Some of the children in the study will be given different medicines. You will not be able to choose which ones you get or be told which ones you're taking. Your doctor and nurse will not know but they can find out if they need to.

From the two inhalers you will be given, you will need to take two puffs from each inhaler, twice a day, (morning and evening) for 12 weeks (3 months). Before taking the inhalers, your parents or carers will test your breathing by asking you to blow out as hard as you can in to a special meter. The nurse will give you and your parents or carers some advice about your inhaler and meter. You will have chance to practice to make sure you're using it properly.

They will give you a special diary that is yours to look after and keep. The nurse will ask you to write in it whenever you have any breathing problems. For example, if you were running at break time at school but had to stop because of your breathing, you should write that in. Your parents, carers or any other adult, like a teacher, can help you fill this in if you need them to. The study nurse will ask about the diary each time they speak to your or your parents or carers.

At the end of the 12 weeks you and your parents will visit the doctor or nurse for a second time to see if the inhaler has helped you. You will need to answer some questions and have your breathing measured again by doing the same tests. They will check that you are well, like they did at the beginning of the study.

Will the medicines upset me?

The medicines we are using have been given to lots of children with breathing problems before so we know they are safe to take. Some children who are given these medicines may get some side effects though. The most common ones are:

- itchy or sore throat
- headaches
- chest infections
- muscle cramps
- croaky voice
- fluttery feelings in the chest (called 'palpitations')
- shaky feeling

Will joining in the study help me?

We cannot promise that joining in the study will help you but we hope that it might do. In the future the information we get from this study might help other boys and girls with breathing problems who are born early.

Are there other sorts of treatment I could have had instead?

Yes. There are a few different medicines used for children with breathing problems. If you were not taking part in the study, you may have been given the medicine your doctor thought would work best for you. The medicines in this study are used to treat children with breathing problems anyway so you might have taken one of them even if you weren't taking part.

Who will know that I am in the study?

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

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?

When you have finished taking part in the study, it will be some time before we know which medication you were on. When the results are available, we shall write to you and your GP, to say which treatment you were on and if there was any improvement with the medication.

What happens if a better medicine comes along?

Sometimes during a research study, new things are found out about the research medicine. Your doctor will tell you about it if this happens. What is best for you might be:

- To carry on taking part in the study
- To stop taking part and have the medicine that the doctor usually uses instead, if they think you need it.

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 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. Your doctor will choose which treatment is best to use instead.

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.

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.

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

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Children's Assent Form

RHINO: Respiratory Health Outcomes in Neonates (RHiNO) (Part 2)

Young person (or, if unable, parent/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
Are you happy to give a sample of you saliva (spit)?	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