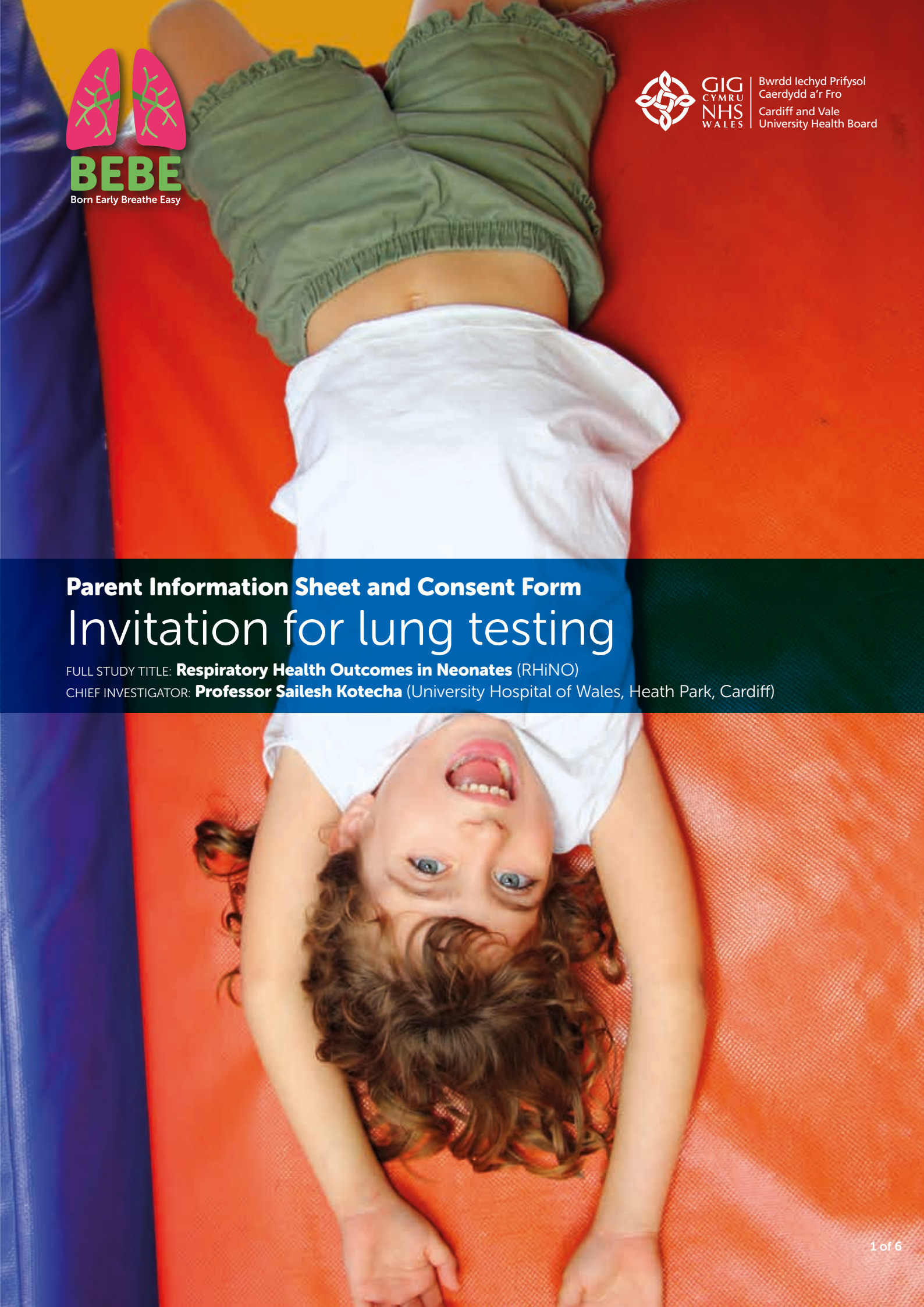

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Parent Information Sheet and Consent Form

Invitation for lung testing

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

Introduction

We are inviting you and your child to take part in a research study. Before you decide if you want your child to take part, it is important that you understand why the research is being done and what it will mean for you and your child. Please take time to read the information leaflet. Please feel free to talk to others about the study and please ask us any questions that you may have or if anything is not clear.

What is the purpose of the study?

We know that children who are born prematurely have breathing problems like wheezing ("whistling in their chest") or shortness of breath but we do not know why. You and your child kindly participated in the first part of the study and we noticed that your child had normal values for their breathing tests. We would like to study children born prematurely with low breathing values but need to compare them to children like yours who were born prematurely and have normal values.

Why has my child been chosen?

You and your child have been asked to take part in this study because they were born prematurely at 34 weeks or less and had normal values for the breathing test when we tested them at home in part 1 of this study.

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

We will arrange for you to visit the RHiNO study clinic at the Paediatric Clinical Research Facility (CRF), Children's Hospital for Wales. The visit will take most of the morning or afternoon (3-4 hours). We will ensure your car parking (if necessary) is paid for and that you are provided with a voucher for a meal after the testing is finished for you and your child. We would like your child to remain in this part of the study for about 3 months.

Once consent has been given, you and your child will be asked some questions to make sure that they are OK to join. They will ask some questions about your child's medical history (including any allergies), what other medicines they may be taking and do a quick examination, including taking their temperature, to make sure they are well enough to take part. A cardiovascular assessment will also be performed which is very similar to taking a blood pressure but also needs an extra cuff to go around your child's thigh as well as their upper arm - this will only take a few minutes. The nurse will then measure their height, weight and body composition (how much muscle and fat they have). We will also perform an allergy 'skin prick' test. For this test your child's skin is lightly pricked with substances to which they might be allergic. This is relatively painless – the skin is gently pricked but it is not punctured. If they are allergic to a given substance, the skin reacts with a small 'hives-like' reaction, and we will measure the size of the reaction.

Next, the nurse or doctor will ask your child to do some breathing and blowing tests and pedalling on an exercise bike to see if they have any signs of narrowing or 'redness' (inflammation) in their breathing tubes. We will demonstrate the tests to your child and let them practise until they are happy to do the tests. Some of the breathing tests will also involve collecting samples of water vapour from their breath and some of their sputum (phlegm). Collecting the water vapour involves simple breathing in and out of a cooled collection tube. To collect the sputum, we will ask your child to breathe in vaporised (nebulised) salty water then cough to bring up the secretions. We would like to collect a urine sample during the visit to check your child's exposure to other peoples cigarette smoke and to measure substances that are increased in other lung diseases. All of these samples can be tested to tell us more about the health of the lungs and airways.

We would also like to collect a sample of your child's saliva (spit) so we can look at some of their genes (DNA) which we think are important for breathing problems and how they respond to different medicines. The saliva sample is optional and it is OK if you would prefer for your child not to provide it - you can still take part in the rest of the study. More information about what will happen to the samples your child provides is given below.

For some of the tests, your child will be asked to sit inside a cubicle with glass doors; the cubicle door will be closed for a few minutes but they will still be able to hear and see us. For the exercise test, your child will be asked to pedal a bike for as long as possible. We expect this to be around 15 minutes. We will closely monitor your child during the exercise test and will stop when your child is too tired to continue or if their heart rate goes too high. After the exercise test, the nurse will then give a small dose of a medicine called salbutamol using an inhaler, before repeating some of the breathing tests to see if the medicine has any effect. The most common side effects are an increased heart rate and headaches. We do not expect these to happen often, but we will check to make sure your child is OK.

We will ensure that your child is comfortable and that there is time for breaks; you will be able to stay with them throughout the tests.

We are also asking for participants to continue writing down results of a blowing test called a 'peak flow' twice a day, for one month after the visit - we will give you and your child a 'peak flow meter' and a diary to write on. You can post this diary back to us in the envelope we will provide.

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 are the other possible disadvantages and risks of taking part?

Although the breathing tests involved in the study are straightforward, it can be tiring to get through the whole set; we will make sure there are opportunities to take breaks and that water is available to drink. Some children may not like the taste of the salty water used to encourage the sputum (phlegm) production, and in some rare cases the salty water can cause the airways to narrow. However, we will only do this test after the exercise bike so that your child will have had a rest and received the 'reliever' (salbutamol) inhaler to open their airways. We will do some blowing tests during the sputum collection to make sure this is OK.

Sometimes, the allergy test liquids can make the skin red, itchy and a bit swollen if the test is positive (a reaction). This wears off quickly and we will have some relief (antihistamine) cream available to make things more comfortable.

What are the possible benefits of taking part?

We are conducting this research so that we know how best to treat children born prematurely who have breathing problems and symptoms. Taking part will not help your child personally but the information we get might help to improve the treatment of children who were born prematurely in the future.

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?

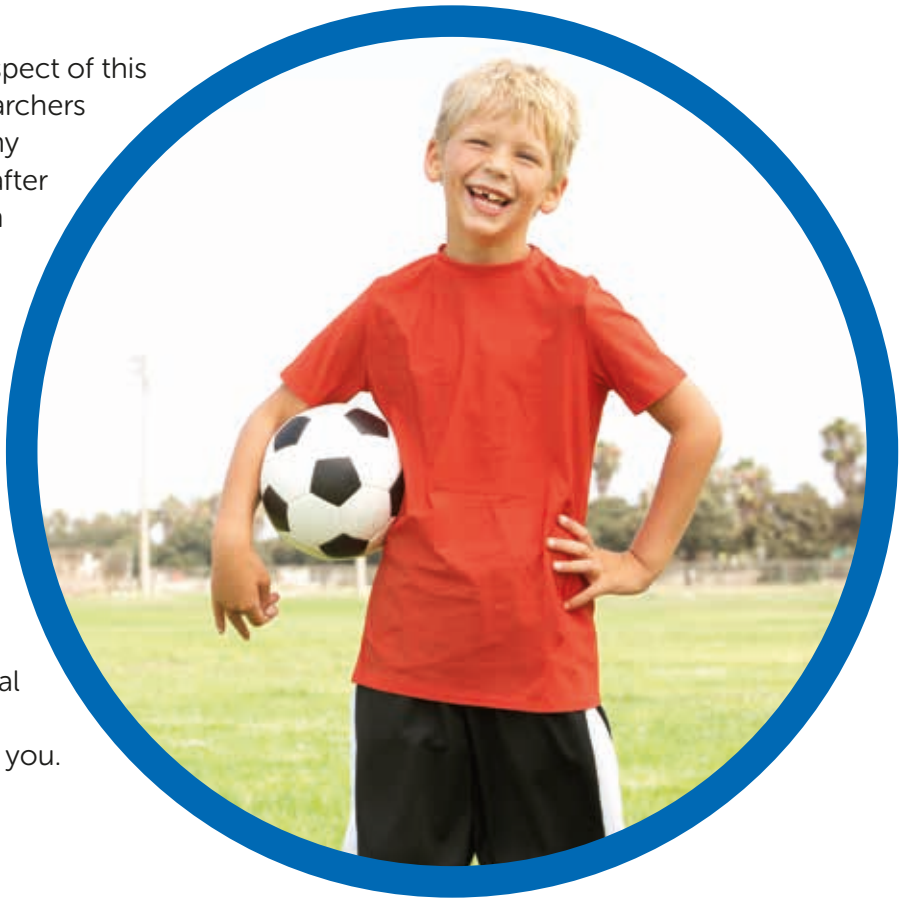
If you have a concern about any aspect of this study you should contact the researchers who will do their best to answer any questions. If you are still unhappy after you have spoken to them and wish to complain formally, you can do this through the NHS Complaints Procedure.

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 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 part 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 any samples my child gives?

All samples (saliva, urine) will be sent to the Department of Child Health at Cardiff University for testing in our laboratory. Some tests may be conducted by commercial companies or other university laboratories which have expertise to analyse the samples. The samples will have a code which means they will not be linked to information about your child.

With your permission any remaining samples, including DNA, may be stored for future research into comparing children who were born prematurely and those who were born at term.

The samples will be anonymised before use in future studies and may be accessed by researchers in the UK and abroad; the research may include genetic (e.g. DNA), commercial and animal research. You may withdraw your consent for the storage and future use of your child's samples at any point. If you do withdraw your consent your child's samples will not be used in any subsequent studies and will be destroyed according to locally approved practices. Any samples already distributed for use in research prior to the withdrawal of consent will continue to be used in that study and any samples remaining at the end of the study will be destroyed.

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 day to day running of the study to the North Wales Organisation for Randomised Trials in Health (NWORTH) at Bangor University.

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

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Parent/Guardian Consent Form

RHiNO: Respiratory Health Outcomes in Neonates (Part 2)

1 I confirm that I have read and understood the information sheet dated 'Version 4 29/07/2016' 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 that 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 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 study.		Initial:
6 I agree to allow my child to take part in the RHiNO study (part 2).		Initial:
7 Optional: I agree to allow a sample of my child's saliva to be taken for use in this study, which will include genetic (DNA) research.	YES NO Please circle	Initial:
8 Optional: I agree for any remaining samples to be used in future for research into children who were born prematurely in the UK and abroad which may include genetic (DNA), commercial or animal research. I understand I am free to withdraw my consent to future research at any point and that all samples will be destroyed as detailed in the information sheet.	YES NO Please circle	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