

BREATHING TOGETHER STUDY

PARTICIPANT INFORMATION SHEET (for parent/guardian)

We are inviting your newborn child to take part in a research study. Before you decide whether your child should take part it is important for you to understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others if you wish.

- **Part 1** tells you the purpose of this study and what will happen to your child if they take part.
- **Part 2** gives you more detailed information about the study.

Please take your time to read this information sheet. If anything is not clear and/or you require more information before you decide whether or not to take part in the study, please contact a member of the study team (details at end of information sheet).

PART ONE

Asthma is one of the commonest long-term conditions in childhood and adulthood. Many children with asthma already have problems with episodes of wheezing by the time they are two or three years old.

It is therefore important for doctors to understand how lungs develop in the first few years of life. At the moment we do not understand this nor why some children start to wheeze or develop asthma. At least a third of babies will develop wheeze before they start school.

We think that problems with the lining of the breathing tubes inside of the lung (the airways) and with the developing immune system are vitally important to the development of asthma.

What is the purpose?

The purpose of this study is to understand how both the lining of the lungs and the immune system develop in well pre-school children and what is different in children who develop asthma. This approach has never been studied before in newborns. We will also assess how allergies and the bacteria in our environment affect the way that the lining of the lungs and the immune system work. We will study the cells from the inside of newborn babies' noses, because they are very similar to those lining the airways, and blood immune cells. We will use the information gained in this study to develop new approaches to prevent children from developing asthma.

Why has my child been invited to take part?

They have been chosen because they have been born in a hospital that is participating in the study.

Do they have to take part?

It is entirely up to you as to whether you wish your child to participate in the study. If you decide that your child will take part, you will be given a copy of this information sheet to keep and you will be asked to sign a consent form. You are free to withdraw your child from the study at any time and without having to give a reason.

What will happen to my child if they take part?

- We will collect some information about your child and their immediate family plus some samples in the ten days after they are born, and then when they are one and three years of age.
- Every month we will send you a very short email to ask whether your child has wheezed. It will take you one minute to respond to. You will be able to watch a short video in order to assess if your child has a wheeze.

What will we do?

For the first assessment we will aim to see your baby when they are five to ten days of age. We will aim to coincide this with your child's Guthrie testing (the heel prick blood sample done for all newborns). We will collect information about your child and their family, collect a urine sample, a brushing from each nostril, a nasal, throat and environmental swab plus some blood (taken when they have their Guthrie testing wherever possible).

Subgroups (your baby can only be in one of these):

- Subgroup 1: Wheezing assessment: once your baby is over six months of age, we would ask you to contact us if they start to wheeze. We would like to see them at the hospital or in your home within three to five days of them starting to wheeze. We would collect some information about your child at this time, collect a nasal brushing from one of their nostrils, a nasal and throat swab and a few drops of blood from a heel or finger prick. Six to eight weeks later we would like to see your infant once again to see how they have recovered and collect a little more blood to see if their immune system has returned to normal.
- Subgroup 2: More detailed microbe assessment: we need to understand how the microbes that live in our nose and throat change during the first year of life. We will ask 100 families over the UK to allow us to additionally take a brushing from one nostril and a nose and throat swab when your child is both three and six months old.

When your child is one year old we will update information about your child and their family, collect a brushing from one of their nostrils, a nasal and throat swab plus a drop of their blood.

For the three year assessment, we will assess your child in a similar way to the one year assessment. We would additionally do some allergy skin prick testing – this is a test we commonly do in clinic which involves dropping some solutions on their arm and scratching them with positive test coming up as a bump.

Collecting samples from your child and what they can tell us:

Urine: we can easily collect this using cotton wool balls. This helps us to assess whether or not they have been exposed to cigarette smoke.

Nasal brushing: we will gently brush each of their nostrils to collect a few of the cells that line the nose. These can tell us how the lining of the airways is working. We routinely use this test in clinic to diagnose respiratory illnesses.

Nasal swab: we will gently swab one of their nostrils to collect some secretions. This will tell us what microbes are living in your child's nose. All of us have microbes living in our nose, throat and lungs; most are harmless.

Throat swab: we will gently rub the back of their mouth to collect some secretions. This will tell us what microbes are living in your child's mouth.

Environment swab: a swab will be taken from your child's environment to see what microbes are inside your home.

Blood: when your baby is five to ten days old they will have a Guthrie test; some blood is taken from their heel; we will aim to collect a few drops of blood for the study at the same time. We can take the later samples in the same way. The blood sample can tell us how your child's immune system is working.

Only some children who start to wheeze in their first few years of life develop asthma. In the future, as a separate study, we hope to follow up children recruited in this study to find out whether or not they developed asthma, other breathing problems or any allergies. This might be by contacting your general practitioner, a telephone/postal/online questionnaire or a clinic visit.

This study does **not** involve the testing of any new medication.

What are the benefits of taking part?

There may be no benefits to your child taking part. However, if they develop wheeze or we find that the allergy tests are positive, we will be able to provide you with additional advice. We will also contact you at the end of the study with a summary of the study results.

Travel and parking expenses will be reimbursed where appropriate.

What are the possible disadvantages and risks of taking part?

We do not think that there will be any risks to your child in taking part. They may experience a little discomfort with the nasal brushing and blood samples.

This completes Part 1 of the Information Sheet. Part 2 will give you more detailed information about the conduct of the study.

PART 2

Will my child's taking part in the study be kept confidential?

All information that is collected about your child during the course of the research will be kept strictly confidential. Personal details (e.g. name) will be kept securely by your local research team and with just limited details shared with the central study coordinator at Imperial College, London. This information will only be used to contact you about the study. Your child will be allocated a study number on all other documentation so that at no time will any of your child's personal details be revealed to researchers. The procedure for handling, processing, storage and destruction of any data collected during the study are compliant with the Data Protection Act 1998.

What will happen to the samples taken in the research study?

Samples collected in the study will go to laboratories in the UK and in Lausanne, Switzerland and Monash University, Melbourne, Australia for analysis. Sometimes we have spare samples, these will be stored and, with your permission, could be used for other studies into breathing problems such as wheeze, asthma and allergies. This may involve collaboration with several other academic institutions; these institutions may be outside the European Union where data protection legislation is not as rigorous as in the UK. However, no identifiable data about you will accompany these samples and there will be no way that any unauthorised person will know the identity of individuals taking part. These studies will have been approved by a research ethics committee.

We will keep all information collected anonymised for up to 20 years, after which it would be destroyed unless there was a good reason and ethical committee approval to retain it. The responsibility of the Chief Investigator would be passed on to another member of the Consortium on the retirement of Professor Bush, the current Chief Investigator.

What will happen to the results of the research study?

The results will be used to help doctors to understand how the lungs develop in the first few years of life and what happens to cause some children to develop asthma. The information will be presented in a clinical study report, which may be used for publication and presentation at scientific meetings. Your child will not be identifiable in any publications arising from this project.

Who is organising and funding the research?

The study is being funded by the Wellcome Trust and is sponsored by Imperial College London.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (see contacts for further information below). If you still have questions or concerns, you can contact Research Governance Office, Imperial College London (telephone number 02075941862).

What if I change my mind after agreeing to take part, and no longer want my child to be part of the study?

You can decide to withdraw your child from the study at any time. This will not affect the way your child is treated at all. You just need to contact the study team at any time and your child can be withdrawn and no explanation at all is needed. If you decide to withdraw your child from the study, we will use the data from the samples that have already been collected for the analysis, but no additional samples or information will be collected.

Who has reviewed the study?

This study was supported by the London – City and East Research Ethics Committee.

How long do I have to decide whether my child should take part?

Your decision to participate in this study is entirely voluntary. You should take as much time as you need to decide whether your child will take part.

Contact for further information

Chief Investigator: Prof Andrew Bush, Imperial College, London, 0207-351-8232.

Thank you for taking the time to read this information sheet.