

# Understanding Asthma study

## Participant Information Sheet



We'd like you to take part in a new research study on asthma. This is a Children of the 90s research study that is also part of a worldwide study taking place in Brazil, Ecuador, New Zealand and Uganda. This study is hoping to understand the different causes of asthma around the world, in richer and poorer countries.

This leaflet explains what we would like you to do and why. Please read it as it will help you decide whether you wish to take part. Before deciding, you can ask us questions about it by calling us on 0117 331 0010 or emailing [info@childrenofthe90s.ac.uk](mailto:info@childrenofthe90s.ac.uk).

### **What is the purpose of the research?**

There are many unanswered questions about what causes asthma and how it works. Whilst asthma can be managed successfully, current treatments don't work for up to half of asthma patients. We think this may be because, for some people with asthma, something is affecting how their nervous system controls their airways.

We want to look at these mechanisms as well as risk factors such as stress. Answering these questions will help us and other asthma researchers develop effective ways to prevent asthma and contribute to improved treatments for all people with asthma.

### **Why have I been invited to take part?**

You do not need to have asthma to take part. We are interested in people who do not have asthma as well as those that do. By looking at both groups of people we can compare the differences between them.

You have been invited to take part because you attended the Focus@24+ clinic and completed a lung function test, or you may have reported that you have asthma in a Children of the 90s questionnaire or at a previous clinic.

### **What will I have to do?**

Attend a 2 hour clinic at Clinical Research and Imaging Centre Bristol (CRICBristol), University of Bristol, 60 St Michael's Hill, Bristol BS2 8DX at a time that is convenient for you. The visit will involve a series of measures which are outlined below.

We might also invite you to a second (shorter) visit three months after your first one where we will repeat the blood pressure, sputum induction, nasal lavage, FeNO and TremoFlotests, and the questionnaire (see below). This is just to make sure that the measures we have taken are accurate, and has nothing to do with your health or the results from your first visit.

1. **Complete a short questionnaire.** We will ask you some questions about your lung health and home environment
2. **Skin prick allergy test on the arm.** We will put ten small drops of liquid allergen on your forearm and then prick each drop to see if you have a positive reaction. This is almost painless and just enough to break your skin. We will be testing for allergies to house dust mite, tree and grass pollen, cat and dog hair and three types of bacteria. You may take part even if you already know that you have an allergy to one or more of the test allergens. If any of the results are positive you may experience some itching, like a nettle sting, on your forearm. Other adverse reactions to skin prick testing are extremely rare. You will receive the results of your skin prick test at your visit.

Ideally, we would like you to avoid using antihistamines (usually used to treat allergic reactions) in the 5 days before your visit, as they can affect the skin prick test result. Of course, if you do need to use an antihistamine please do so but let us know on the day of your appointment.

3. **Blood pressure measurement.** We will measure your blood pressure twice while you are sitting down by placing a cuff around your upper arm. The cuff will inflate (blow up) for a moment and then deflate (let out the air) slowly. There are no risks involved, although the cuff may feel a little tight and uncomfortable for a moment.

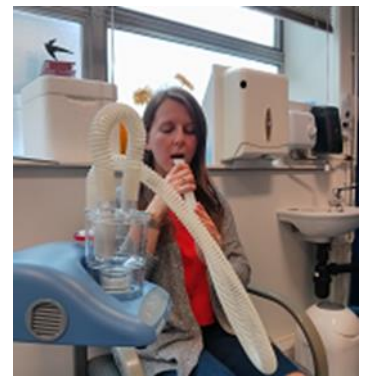
4. **Lung function test.** This will involve blowing into a special machine as hard as you can for a few seconds. You may feel breathless for a short period, although generally this test causes no discomfort. We may ask you to do this again after inhaling a common asthma drug called salbutamol. This is very safe and usually used to treat asthma. If you have recently attended Focus@24+ you will have already completed a lung function test and may not be asked to do it again.



Lung function test in progress

**FOR ASTHMATICS ONLY: Using an asthma inhaler before your visit.** If you use an asthma reliever inhaler (taken when wheezy, such as Ventolin) we would like you to stop using it for at least six hours before your visit. If you use an asthma preventer inhaler (usually taken every day whether wheezy or not) we would like you to stop using it for at least 12 hours before your visit. This includes long-acting bronchodilators such as salmeterol (Serevent) and formoterol (Oxis). If you use a long acting oral treatment, known as theophyllines, usually taken in the form of a daily or twice daily tablet e.g. Austyn, Neulin, Siobid or Theo-Dur please stop taking this treatment 24 hours before your visit. However, if you have an asthma attack or are short of breath you should use your inhaler as normal and please let the Research Nurse know when you come in. If you are unsure of your inhaler type please contact us and we will be able to advise you. If you are on medication, please bring it with you to the clinic.

5. **Sputum induction test.** This test involves inhaling salbutamol, then breathing in a fine spray of saline solution (slightly salty water). After a few minutes of breathing the spray, you may cough and we will collect what you cough up (sputum) and analyse it. Depending on how much you cough up, we may ask you to do this just once or several times, for no more than 16 minutes in total. This may feel a bit like having a cough or cold.



Sputum induction test in progress

Doing this may irritate the back of your throat and affect your breathing. If this happens, we will ask you to inhale some salbutamol again. A trained nurse will do this test and monitor your breathing carefully throughout.

6. **Nasal lavage sample.** We will spray a fine mist of saline solution (slightly salty water) into your nostril through the end of a syringe, then we will ask you to tip your head forward to blow the solution out through your nose into a tube to collect the solution for analysis. This may feel a bit like getting water up your nose when swimming but is unlikely to cause any other discomfort.

**If you use a steroidal nasal spray for an allergy e.g. hayfever or other reason (e.g. runny nose), we will ask you not to take this treatment for 7 days before your test. Nasal sprays include products containing beclometasone, budesonide, fluticasone, mometasone and triamcinolone. However, if you have a flare up of your allergy, please take your medication as usual and tell us when you visit the clinic.**

Other treatments that may affect the research results are non-steroidal anti-inflammatories. These are usually used for conditions such as headaches, painful periods, sprains and strains, colds and flu, arthritis, and other causes of long-term pain. Commonly used products are ibuprofen, naproxen, diclofenac and celecoxib. **We ask that you do not take any non-steroidal anti-inflammatories for 6 hours before your visit.** However, if you need to use a non-steroidal anti-inflammatory in the 6 hours before your visit, please do so and tell us on the day.



Left: Nasal lavage in progress

Right: The syringe and atomiser used in nasal lavage



**7. Blood sample.** We will take a small blood sample from your arm and use it to check the levels of proteins that can cause your airways to get inflamed. We will also count the number of red cells, white cells and platelets in your blood. You might find this slightly uncomfortable and your arm may have a temporary bruise. You can eat and drink as normal before giving blood.

**8. FeNO (fractional exhaled nitric oxide) test.** This test involves you breathing in as deeply as you can through a special mouthpiece attached to a machine and then slowly breathing out into the machine at a constant rate. You may feel breathless for a very short period, although generally this test causes no discomfort. We will ask you to do this twice. This test provides a measure of allergic inflammation in the air passages of the lungs. There are no risks or side effects from doing the test.



FeNO measure in progress

**9. TremoFlo (airwave oscillometry system) test.** This test involves breathing as normally as possible into a special machine for at least 16 seconds. When you breathe the machine will pass tiny airway vibrations into your airways, which feels

like a flutter. We will ask you to do this test three times. There are no risks or side effects from doing the test. TremoFlo measures natural resistance to air flow in different parts of your lung and is another measure of lung function.



TremoFlo measure in progress

*Please note: You can stop any of the tests at any time.*

### **What will you do with my samples?**

We will measure the number of cells in your sputum, nasal lavage and blood samples, and measure them for chemicals naturally produced by the body in response to inflammation. We will also extract genetic material from your samples. These will be used for genetic studies and epigenetic analysis, for example, to see if DNA from your sputum (taken from the lung) works differently to DNA from your blood. We will also be storing samples for future use if you agree to this.

### **Am I eligible to take part?**

You will not be able to take part if:

- You have had lung or chest problems or diagnoses, colds, or hospital admissions in the past four weeks
- You are taking long-term medication (other than for asthma)
- You have a history of chronic lung or chest disease (other than asthma) or heart disease (including high blood pressure)
- You are pregnant
- You have had an acute asthma attack which required an increase in your usual treatment in the past four weeks

If you are unsure if you are eligible but wish to take part please write this on the reply slip and we will get in touch. For example, we may be able to reschedule your appointment if you have been unwell.

### **Do I have to take part?**

No - it is up to you to decide whether to take part. If you decide to take part, you can withdraw from the research at any time and you can choose to take part in the first visit but not the second one. If you decide not to take part it will not affect any other Children of the 90s activities that you or your family may be involved in.



**Where will it take place?**

CRIC Bristol, University of Bristol, 60 St Michael's Hill, Bristol BS2 8DX

**How long will it take?**

The first clinic visit should last about an 2 hours. If you are invited for the second visit it should take about an hour and a half.

**Will I receive anything for my time?**

As a thank you we will offer you £20 in shopping vouchers for your first clinic and £10 for the second (shorter) one. We will also reimburse your travel and accommodation expenses and can provide a taxi to CRIC Bristol or free parking at Children of the 90s (a 10-15 minute walk from CRIC), if required.

**Are there any benefits to me if I take part?**

There are no direct health benefits to you for taking part, and this is not a health check; we are asking you to help us with research that could help people in the future. If you have any symptoms that cause you concern at any time, you should always contact your GP.

You will have the option to receive results for the skin prick allergy test. With your consent, we will give you a letter to take to your GP about the skin prick allergy test results if you had an allergic reaction.

If your blood pressure is higher than normal, we will give you a letter to take to your GP.

If you do not currently have asthma and the lung function test gives cause for concern, and if you have given us consent to do so, we will contact you and then send you a letter to give to your GP within three months of your visit. If you have asthma we will not contact you or send you a letter for your GP as you will already have had a diagnosis.

If your FeNO tests shows that your lungs may be inflamed, we will give you a letter to take to your doctor.

If the cell count in your blood shows that you may have a serious health issue we will contact you as soon as possible, usually within a few days of your clinic visit. We will only do this if you have given us consent to do so.

**Are there any risks or disadvantages if I take part?**

We have outlined the low-level risks associated with each of the tests above. There are also some side effects of the drug salbutamol used as part of the lung function and sputum induction tests. However, the side effects with the dose used are rare. The most common of these is a mild tremor (which affects fewer than 1 in 100 people). Other side effects can be anxiety, headache, muscle cramps, dry

mouth and palpitations. These usually only occur in higher doses or after repeat use. These occur in fewer than 1 in 1000 people. Other than your time, there are no anticipated disadvantages in taking part.

### **What do I have to do now?**

If you want to take part, please complete the enclosed reply slip and return it to us in the freepost envelope provided. Alternatively, call or email using the contact details over the page. If you don't want to take part please let us know so we don't send you any more reminders about this study.

### **Confidentiality and data protection**

Your information will be stored with an individual ID number but not with your personal information attached (such as your name, address or date of birth). Files that link this ID number to your personal details will be securely stored and only a restricted number of Children of the 90s staff will have access to them. The data will be used for research purposes only and will be analysed by Children of the 90s approved researchers. None of these researchers will have access to your personal information.

A lot of the research using your samples will take place in Bristol but some of your samples may be made available to researchers working in universities, hospitals or other organisations in the UK or abroad. We may ask for a fee from researchers to help cover the costs of storing your samples as well as the costs associated with sending them to other places. We will not sell or make any profit from the samples you donate and they will only be used in ethically approved research.

The results of the study will be published in scientific journals and a summary of the results will be provided to all study participants. No individual information or names will be published.

### **What if something goes wrong? What if I have questions or concerns?**

As with all Children of the 90s studies, the University has legal liability insurance in the unlikely event that any participant is injured due to negligence on the part of the University or its employees. If you have questions or concerns about any aspect of this research, please contact Children of the 90s (0117 331 0010, [info@childrenofthe90s.ac.uk](mailto:info@childrenofthe90s.ac.uk)). If we are unable to answer your question or concern directly we will talk to the lead researcher and get back to you as soon as possible.

### **Who is organising and funding the research?**

This research is organised by Children of the 90s. Professor Neil Pearce, London School of Hygiene and Tropical Medicine, is overseeing the project worldwide. Professor John Henderson is the lead researcher at Children of the 90s.

The research has been funded by the European Research Council. In addition, Children of the 90s receives core funding from the Wellcome Trust, the UK Medical Research Council and the University of Bristol.

### **Who has reviewed this research?**

- Anonymous reviewers and grant board members for the European Research Council
- Children of the 90s executive committee
- Children of the 90s ethics and law committee (ALEC)
- Children of the 90s original cohort advisory panel (OCAP)
- An NHS Research Ethics Committee.

### **Contact for further information**

Tel: **0117 331 0010** Email **info@childrenofthe90s.ac.uk**

**Thank you for taking the time to read about our asthma research  
and for your ongoing support of Children of the 90s.**