

## **PARTICIPANT INFORMATION SHEET - Isle of Wight Birth Cohort study- 26 year follow-up**

We would like to thank you for your involvement so far in the 1989/1990 birth cohort. The data we have been able to collect from you has been tremendously helpful in advancing understanding of asthma and other allergic diseases.

You are now being invited for a follow-up as part of this study. Before you decide to participate it is important for you to understand why the research is being done and what it will involve.

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

Please read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

### **Part 1**

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

Over the last few decades there has been a dramatic increase in the number of people with asthma, eczema, hay fever, food allergy and lung disease. We still do not know why some people develop these diseases or why some people with these diseases appear to outgrow them. If we can gain a better understanding it may provide us with new ideas for treating or even curing these diseases.

We are also continuing our work to understand how our genes are involved in the development of asthma and other allergic and lung conditions. Certain genes have been linked with these diseases but we need to undertake further research work to better understand this link. If we are to maximise our chance of discovering how our genes are involved in the development of asthma and other allergic conditions, we need to look at the genes of as many of the group as possible including those who are completely healthy. We can do this by taking a small amount of blood from you.

#### **Why have I been chosen?**

You have been chosen because you are part of the Isle of Wight Birth cohort. This is a birth cohort of nearly one-and-a-half-thousand young people all born on the Isle of Wight in 1989 and early 1990.

#### **What will happen to me if I take part?**

We will arrange for you to visit the David Hide Research Centre at a convenient time, or you can even drop in to the centre if you happen to be passing the hospital between 9am and 3pm and we will do our best to see you straight away. We will reimburse your travel expenses. We will repeat some of the procedures that you may have been asked to do at previous visits. Even if you have not visited us before we would like you to participate this time by undertaking all or part of the following:

- Questionnaire about your current health and lifestyle
- Weight, height and blood pressure, and check whether you have signs of eczema or asthma
- Breathe into a machine to measure the amount of nitric oxide in your lungs. This tells us if you have inflammation in your lungs which will affect how they work.
- Lung function measurements – we will ask you to blow into a computer to check how well your lungs are working, before and after 400 to 600 mcg of salbutamol given with an inhaler. This may improve your lung function.
- Skin prick test – this is a safe, standard medical test for allergies (eg house dust mite) that most of you will have experienced before; a drop of each test liquid will be put on the skin and gently scratched; the test is positive if a small wheal develops after 15 minutes.
- We would like to take a small amount of blood. If you wish, we can use anaesthetic cream to numb the skin beforehand. You do not have to give a blood sample if you do not wish to.
- Urine – we will ask you to provide us with a small urine sample
- We may request a saliva sample from you

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

We will ask you to come to the David Hide Asthma and Allergy Research Centre, at a convenient time, for a visit that should last approximately one and a half hours. You can even drop in to the centre if you happen to be passing the hospital between 9am and 3pm and we will do our best to see you straight away. Before your visit we will ask you not to eat any food for 2 hours and not to drink or eat any caffeine (eg coffee, tea, coke, chocolate) for 6 hours; if you take asthma medication please do not use your reliever inhaler (eg ventolin, salbutamol, terbutaline, bricanyl) for 4 hours; long acting inhaler (eg salmeterol, serevent, seretide, eformoterol, oxis, symbicort, fostair, flutiform, relvar ellipta) for 12 hours; and antihistamines for 72 hours. If you believe this will be difficult for you please contact the research nurses or doctor to discuss. If you have had a respiratory

infection in the previous 2 weeks or are taking oral steroids we will rebook your visit at a convenient time for you.

### **What are the possible disadvantages and risks of taking part?**

The skin prick test and blood test may cause some slight, temporary discomfort.

In the highly unlikely event of any injury caused to you, medical care through the National Health Service will be available to you. St. Mary's Hospital NHS Trust has indemnified this study.

### **What are the possible benefits of taking part?**

Your participation so far in this study has been invaluable by allowing us to see how asthma and allergies affect children and teenagers as they grow up. The further information we learn from this follow-up will help us to understand why some people with asthma and other allergic and lung conditions improve, while others continue to have problems throughout their adult life. It will also help us understand why people develop new health problems in early adult life.

Your participation is equally important whether you have any medical conditions or not, as we need to study both healthy and those with symptoms to know how these diseases are caused and how we can be better at preventing or treating them. This is critically important as more of us are developing these illnesses.

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

It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. The first part of the consent form (Part A) asks for your consent to participate in the study. The second part (Part B) asks for permission to store any unused blood or other samples for use in future research into asthma, lung and allergic diseases. The samples will only be used for studies approved by the Local Research Ethics Committee. The samples will be fully anonymous to the researchers who use them but contain codes that would allow the clinical study team who collected them to link them back to you. You are free to choose to just sign Part A and not sign Part B. You will receive a copy of the signed consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the medical care you receive.

### **Photographs for Promotional Use**

We would like to take a few photos of participants taking part in the various test, we would use these photos purely for promotional purposes and to aid with presentation of the data at medical conferences. It is optional for you to have photographs taken and used in this manner, if you agree, we will ask you to sign an additional consent form.

### **What if there is a problem?**

If you have any questions or concerns, please contact Dr Ramesh Kurukulaaratchy or Dr Claire Hodgekiss at The David Hide Asthma and Allergy Research Centre, St Mary's Hospital, Newport, Isle of Wight. Telephone: 01983 530786. Email: [IOWstudy@iow.nhs.uk](mailto:IOWstudy@iow.nhs.uk).

### **Will my taking part in the study be kept confidential?**

Yes. All the information about your participation in this study will be kept confidential.

### **Contact for further information**

Claire Hodgekiss or Ramesh Kurukulaaratchy, The David Hide Asthma and Allergy Research Centre, St Mary's Hospital, Newport, Isle of Wight. Telephone: 01983 530786. Email: [IOWstudy@iow.nhs.uk](mailto:IOWstudy@iow.nhs.uk).

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

## **Part 2**

### **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 (Claire Hodgekiss 01983 530786). If you still have questions or concerns, you can contact Alex Punter (Lead for Research and Development, St Mary's Hospital, Newport, Isle of Wight, PO30 5TG; email [alexandra.punter@iow.nhs.uk](mailto:alexandra.punter@iow.nhs.uk)).

In the very unlikely event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against St Mary's Hospital but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### **Will my taking part in this study be kept confidential?**

The personal information collected in this study will be kept confidential. The data we collect from you will not be labelled with your personal details and will be stored securely. Data collected during the study will be shared with

our research collaborators in other universities in the UK, Europe and USA; however they will not know who the information belongs to as your name and address will not leave The David Hide Asthma and Allergy Research Centre. Only the study personnel will have access to your personal details. You will not be individually identified in any reports or publications resulting from the study. We will keep your data on file for use in future studies approved by the Research Ethics Committee.

### **Involvement of the General Practitioner**

We would like your permission to notify your General Practitioner (GP) of your participation in this study. With your permission we would send your GP the results of your tests as they may be useful for your future medical care. We would not send your GP any other information from the study.

### **What will happen to any samples I give?**

*Blood:* we will use this to check how allergic you are and will extract genetic material from the sample. This will only be used to look for genes that may be involved in the development of allergies, asthma and other lung disease and related conditions.

*Urine:* we plan to measure the level of cotinine in this sample, this increases if you have been exposed to cigarette smoke, passively or otherwise. The result will not be released to your doctor or anyone else.

Samples will be stored securely at the David Hide Asthma and Allergy Centre until they are analysed. Only the researchers at the Centre will have access to them. Some of the blood, samples will be analysed outside of St Mary's Hospital (including in the USA). The samples will not be labelled with your name or address so that the researchers analysing them will not know that the sample belongs to you. With your permission, we would like to store some blood for use in further studies into asthma, allergy and lung disease. We will only use these stored samples for studies reviewed and approved by the Research Ethics Committee.

### **Will any genetic tests be done?**

As we explained in the "What is the purpose of the study?" section above, we are looking at which of our genes are involved in the development of asthma and other lung and allergic diseases. For this work we can use the blood samples. The results we obtain will help us to understand why some people develop asthma, allergies and lung disease. The results will not directly help you and will not have any individual significance to you so we will not be able to give you your individual results.

### **What will happen to the results of the research study?**

We aim to publish the results of the study in medical journals so that other doctors and researchers can make use of them. This is likely to be accompanied by an article in the local press on the Isle of Wight and sometimes in the national media. It will not be possible to identify any individual person involved in the study from these published results.

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

The researchers at The David Hide Asthma and Allergy Research Centre are organising and carrying out this study. This study is being supported by Southampton Respiratory Biomedical Research Unit, which is funded by the National Institute of Health Research, UK. They are also being helped by a group of experts from Michigan State University and University of Memphis in the United States of America, who will provide the expertise to analyse the blood samples and analyse the data collected.

### **Who has reviewed the study?**

This study was given a favourable ethical opinion for conduct in the NHS by NRES Committee West Midlands – Edgbaston, reference number 15/WM/0071.

### **How long do I have to decide whether I should take part?**

Your decision to participate in this study is entirely voluntary. You should take as much time as you need.

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

**THE DAVID HIDE ASTHMA AND ALLERGY RESEARCH CENTRE  
St Mary's Hospital, Newport, Isle of Wight PO30 5TG. Tel: 01983 530786**