

## **MeDALL**

Mechanisms of the Development of ALLergy

### **Please read this information sheet carefully**

**We would like to invite you and your child to take part in this research study.**

#### **Why are we carrying out this study?**

MeDALL is trying to find out what happens in early childhood that seems to 'trigger off' allergic diseases such as asthma and eczema in very young children. Over the last 20 to 30 years more and more children have been developing allergic diseases such as asthma and eczema both in the UK and in other developed countries. It is unclear why this is the case and although there have been many studies across the world exploring this problem knowledge is limited and answers are largely unknown.

MeDALL will work together with families in Born in Bradford (BiB) and families from another 12 similar types of studies across Europe to bring together all the information already collected and to gather new data. By working together with so many other birth cohort studies we will be able to obtain important information from over 50,000 children and their families.

Whether you decide to take part in the project is entirely up to you. If you decide you want to, then later you change your mind you can withdraw at any time. Whatever you decide your child's medical care will not be affected in any way. If you do join the study we will tell your GP that you are taking part. You can continue to take part in Born in Bradford if you do not want to join this study.

As part of the research a member of the Born in Bradford team will contact you by telephone to see if you are interested in knowing more about the study before considering taking part.

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

If you agree to take part after reading this information sheet a community research administrator (CRA) experienced in working with young children, will ask to see you once when your child is four years old. We will see you at a time and place that is convenient for you; either in your own home or at Bradford Royal Infirmary.

As part of the research you will be asked to sign a consent form to agree to take part in the following:

- complete a questionnaire which takes approximately 20 minutes
- have your child weighed and measured
- carry out a test to see how well your child's lungs are working (spirometry).
  - We ask the child to blow into a mouth piece connected to a computer to measure the amount of air entering and leaving the lungs
- perform a clinical skin examination if your child has any patches of skin irritation.
  - The CRA will look at your child's skin and ask if she can record and measure any patches of irritation (e.g. eczema) which may be present; she will also ask if this has any negative effects on your child's life

## **You will also be asked to sign a separate consent if you agree to your child having:**

- **a skin allergy test** to see whether your child is sensitive to the most common irritants such as dog, cat and grass, and dust mite (a separate information sheet is enclosed with more details about what this involves)

### **and/or**

- **a blood sample taken**

This is a very important blood test because it will tell us if your child has an allergy and what they are allergic to. We can then use this information to investigate the causes of allergy and infection. ----- If you agree to have the blood sample taken, the community research administrator, who is very skilled in taking blood from young children, will take a small amount of blood (1-2 teaspoons) from your child's arm. Your child may experience slight discomfort when the blood sample is taken. We reduce the risk of this by numbing the skin on your child's arm with anaesthetic spray beforehand and our team of CRAs are very experienced in working with young children and highly skilled at taking blood from them.

### **and/or**

- **a swab taken from the inside of your child's cheek (buccal smear)**

This is an easy way to collect cells from the mouth by rubbing a swab against the inside of your child's cheek. By examining the genes of these cells, we can find out how environmental factors may alter the risk of disease.

## **You can still take part without agreeing to these parts of the study.**

The whole visit should take no more than one hour. Despite motivation and encouragement it may not always be possible to complete the tests you may have consented to. If your child gets distressed or is unwilling to take part in any of the tests we will not continue with the test.

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

By taking part in this study you will help us to understand more about how children develop allergic diseases such as asthma and eczema. It is also anticipated new tools to enable early diagnosis of allergies will be developed as well as new ways to treat and prevent allergic diseases. This information is likely to help to improve the health of many children in the future.

## **What will happen to the information we collect?**

The information collected for this study will be stored in strict confidence, as is required by the Data Protection Act. A study number will be the only way information will be linked to you. Only certain members of the study team will be able to link you to the information we have collected about you. We will link the information collected in this study to the data collected for Born in Bradford. The Bradford Research Ethics Committee, established by the Health Research Authority and the Bradford Teaching Hospitals research and development department have approved the project.

## **How will I find out the results of the study?**

The findings from the study will be published in scientific journals. We will also make sure that those taking part will hear about the results through public meetings, Children's Centre groups and the BiB newsletter. None of these publications or presentations will identify individual participants.

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

This study is co-ordinated by Dagmar Waiblinger at Bradford Teaching Hospitals NHS Foundation Trust and other Born in Bradford staff are also involved. The study is funded by the European Union. If you wish to take part or have any questions about the project or just want to know more about the work we are conducting please contact the Born in Bradford community office on 01274 383454. We will answer any questions you may have.

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

