



(To be presented on local headed paper)

Centre Name:  
Centre Number:

## **MASCOT – Management of Asthma in School-age Children On Therapy**

**Children's (6-10 Years) Information Sheet and Consent Form (v2.0,  
24.07.2008)**

We thank your mum or dad for helping you to read this information.

### **What is a research study? Why is this study being done?**

A research study is what you do when you want to learn about something or find out something new. It can help doctors and nurses and other people in the hospital find out which are the best medicines to use.



This study looks at two different medicines called Salmeterol and Montelukast. These are called 'add-on' medicines because we want to see whether they make another medicine, Fluticasone, work better than it does on its own. All three of these medicines are both used already to help children with asthma. We don't know for certain though if Salmeterol or Montelukast make Fluticasone work better or if it works just as well on its own. If the add-on medicines do make Fluticasone work better we want to know if they do this as well as each other or if one is better than the other.

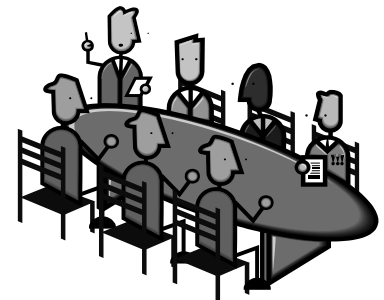
## Why was I asked to take part?

You were chosen to take part because you have asthma and the medicines you are taking at the moment don't work as well as they could.

This study will involve about 900 children like you in Britain.

## Did anyone else check the study is OK to do?

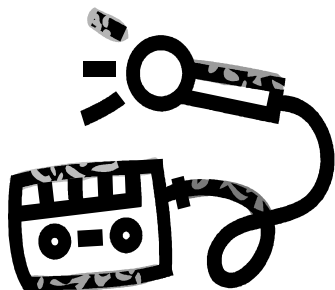
Before any study is allowed to happen, it has to be checked by a group of people called an Ethics Committee. The Ethics Committee is a group of experts and ordinary people who look at studies very carefully to decide whether they are OK to do. The North West Research Ethics Committee have looked at this study and decided it is OK.



## Do I have to say yes?

No – not at all. It's up to you! Just say if you don't want to take part. Nobody will mind.

If you do take part, you will need to write your name on a form called an 'assent form'. This form is to say that you understand the study and what will happen if you join. You will be given your own copy of this form to keep as well as this information sheet.

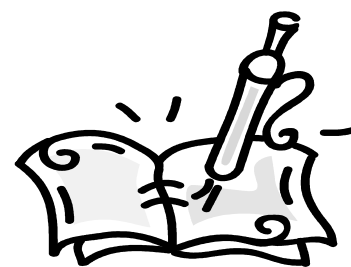


Your study doctor or nurse may also ask if you mind them recording themselves talking to you about the study. This is because a study called **RECRUIT** is being done to find out what it is like for parents and children when they are asked to take part in a study. If you say yes, the study doctor or nurse will give your contact details to the researchers running the RECRUIT study. The RECRUIT researchers might then contact you to ask some more questions. If you decide you do not want anyone to listen to the recording, that is OK too and it will be deleted.

## What will I need to do and how long will it take?

At your first visit you will see either the study doctor or nurse and they will talk to you about the research. If you say yes to joining the study, you will need to answer some questions and tell the doctor or nurse about how your asthma affects you. They will also check you over to make sure that you are well enough to be in the study.

The nurse will give you and your parents some advice about your inhaler to make sure you're using it properly. They will give you a special diary that is yours to look after and keep. The nurse will ask you to write in it whenever you have any asthma symptoms. For example, if you were playing football at school but had to stop because of your breathing, you should write that in. Your parents or any other adult, like a teacher, can help you fill this in if you need them to. The nurse will ask to look at the diary every time you come to see them. The doctor or nurse will also give you a new inhaler to use for the next four weeks.



After four weeks you and your parents will go back to the doctor or nurse and they will ask if you still want to join in the study. He or she will ask you how your breathing has been since they last saw you and will measure how much air you can blow out of your lungs in one big breath. If everything is OK and you still want to be in the study your parents will be given your medicine.



Some of the children in the study will be given different medicines but you will not be able to choose which ones you get. You will not be told which ones you're taking. Your doctor and nurse will not know but they can find out if they need to.

**You will need to take one suck from your inhaler twice a day and one tablet a day for 48 weeks.** You and your parents will visit the nurse three more times during the 48 weeks and they will look through your special diary with you and ask how your breathing has been.

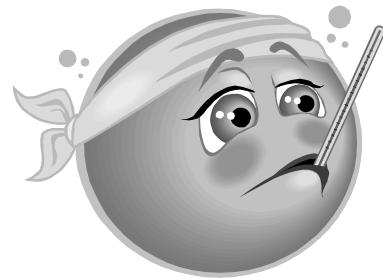


At the end of the research you and your parents will visit the doctor or nurse one last time. You will need to answer some questions and have your breathing measured again. They will check that you are well, like they did at the beginning of the study.

### **Will the medicines upset me?**

Fluticasone, salmeterol and montelukast have been given to lots of children with asthma before so we know they are safe to take. Some children who are given these medicines may get some side effects though. The most common ones are:

- itchy or sore throat
- chest infections
- croaky voice
- headaches
- muscle cramps
- shaky feeling (called 'palpitations')



### **Will joining in the study help me?**

We cannot promise that joining in the study will help you but we hope that it might do. In the future the information we get from this study might help other boys and girls with asthma.

### **Are there other sorts of treatment I could have had instead?**

Yes. There are a few different medicines used for children with asthma. If you were not taking part in the study, you would have been given the medicine your doctor thought would work best for you. The medicines in this study are used to treat children with asthma anyway so you might have received one of them even if you weren't taking part.

### **Who will know that I am in the study?**

The study doctor and nurse who are taking care of you will know. So will the doctor who usually looks after you and the study pharmacist (the person who gives you your medicines).

### **How will the information about me be kept private?**



Everything you tell us is private. The only time we would ever tell somebody what you have said is if something made us worried about you. All information collected for this study will be kept safely on the computer or as paper records. Of course, you can tell your family and friends about the study if you want to.

### **What happens when the research stops?**

When you have finished taking part in the study, your usual doctor will be told what medicines you were taking. Your parents can find out from them what medicines you were taking if they want to.

### **What happens if a better medicine comes along?**

Sometimes during a research study, new things are found out about the research medicine. Your doctor will tell you about it if this happens. What is best for you might be:

- To carry on taking part in the study
- To stop taking part and have the medicine that the doctor usually uses instead.



### **What happens if there is a problem with the study?**

If you think there are any problems with the study or if you have any worries about it you can tell your parents. You can also tell the study nurse (their name is at the end of this

leaflet). They will do their best to answer your questions. If you are still unhappy you can talk to someone else. Your parents will probably be the best people to talk to.

### **What if I don't want to do the study anymore?**

If you want to stop the study at anytime, just tell your parents, study doctor or nurse. They will not be cross with you. If you say no or want to stop the study at any time it will not change the way the doctors and nurses will look after you. Your doctor will choose which treatment is best to use instead.

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

We will write reports for the doctors and nurses who look after children with asthma. The results will also be written in special magazines (scientific journals). No-one will know that they are your results because your name will not be written on them. We will send you a report telling you the results at the end of the study if you would like us to.



### **What shall I do now?**

Now you know about the study you need to think about whether you want to join or not.

**Who can I talk to for more information?**

If you have any questions at all, at any time, please contact:

Study nurse name, telephone and email

The other people helping with this study are:

**Research Doctor:**

**Tel:**

**Thank you very much for taking time to read this. Please ask any questions if you need to.**



## **MASCOT – Management of Asthma in School-age Children On Therapy**

**Assent Form for Children (v2.0, 24.07.2008)  
(to be completed by the child and their parent/guardian)**

**Child (or, if unable, parent on their behalf) to circle all they agree with:**

- Have you read (or had read to you) the information about this study?    Yes/No
- Has a doctor or nurse explained this study to you?    Yes/No
- Do you understand what this study is about?    Yes/No
- Have you asked all the questions you want to?    Yes/No
- Have you had all of your questions answered in a way you understand?    Yes/No
- Do you understand that it's OK to stop taking part at any time?    Yes/No
- Are you happy to take part in this study?    Yes/No
- Are you happy for this conversation to be recorded for RECRUIT?\*    Yes/No  
(\*delete if not applicable to this centre)

If ANY answers are 'No' or you don't want to take part, DON'T sign your name!

If you **DO** want to take part, please write your name and today's date below:

Your name \_\_\_\_\_

Date \_\_\_\_\_

Your parent/guardian must write their name here too if they are happy for you to take part:

Sign \_\_\_\_\_

Print \_\_\_\_\_

Date \_\_\_\_\_

The doctor or nurse who explained this study to you needs to sign too:

Sign \_\_\_\_\_

Print \_\_\_\_\_

Date \_\_\_\_\_