

PARENTS' INFORMATION SHEET

The Born in Bradford Infection and Allergy Study

Please read this information sheet carefully

We would like to invite you and your child to take part in this research study. We are trying to find out whether common childhood infections play a role in the development of diseases such as asthma, hay fever and eczema.

Why are we carrying out this study?

There is a lot of scientific evidence that infections early in life may affect the risk of disease later in life. Over the last 20 to 30 years more and more children have been getting asthma, eczema and other allergic diseases both in the UK and in other developed countries. We do not know why but one possibility is because common infections early in life have become less frequent.

The aim of the project is to find out if some common viral infections which children catch when they are very young affect the way their body copes with diseases in the future. In particular we are interested to see if these infections play a part in the development of diseases such as asthma, hay fever and eczema. We will also study whether these infections alter the children's response to routine vaccinations. In the future, vaccines may be introduced against the viral infections that we are interested in. It is important to find out what the benefits or risks of these vaccines might be.

We are asking all families taking part in Born in Bradford if they would also consider taking part in this study. You can continue to take part in Born in Bradford if you do not want to join this study.

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

Whether you decide to take part in the project is entirely up to you. If you decide you want to do it, 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.

As part of the research someone from the Born in Bradford team will contact you by post or telephone to see if you are interested in knowing more about the study before considering taking part. If you agree a family study worker will visit you and your child at your home **when your child is about one year old** and **again when your child is about two years old**, at a time that is convenient for you.

As part of the research you will be asked to sign a consent form and at each visit:

- complete a questionnaire with the help of a family study worker; this takes approximately 30 to 40 minutes
- your child will be weighed and measured
- if you agree, the family study worker, who is very skilled in taking blood from young children, will take a small amount of blood (about a teaspoonful) from your child's arm

Later when your child is about 4 years old we will contact you again to see if you would be willing for your child to be tested for allergies. We will give you more information then about the

skin prick tests which are used to test for allergies and we will ask you to sign another consent form if you wish to take part. Please let us know if you would like to see the information about allergy testing now.

What are the possible disadvantages of taking part?

Your child may experience slight discomfort when the blood sample is taken but we reduce the risk of this by numbing the skin on your child's arm with anaesthetic cream beforehand and also by using family study workers who are very experienced in working with young children and highly skilled at taking blood from them. This blood is needed because most children do not have symptoms of the infections we are studying. Therefore we need to test their blood to find out if or when they became infected.

What are the possible benefits of taking part?

- You will be notified if the tests show that your child is not protected against measles or tetanus for which they have received routine vaccinations. This is very unlikely but occasionally routine vaccinations do not work. In this case you will be advised to contact your GP about further vaccination. These tests will be done some time after the blood sample is taken so you will not have the results immediately.
- By taking part in this study you will help us to understand how the immune system develops and why some children have diseases like asthma and eczema. This information is likely to help many children in the future.

What will happen to the information we collect?

The information collected for this study and the blood samples collected will be stored in strict confidence, as is required by the Data Protection and Human Tissues Acts. 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. Individual results of tests for infection will not be available. We will link the information collected in this study to the data collected for Born in Bradford.

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 Dr Lucy Pembrey and Professor Andrew Hall at the London School of Hygiene and Tropical Medicine, Professor John Wright and Dr Pauline Raynor from the Bradford Institute of Health Research and Professor Chris Wild from the University of Leeds. Other Born in Bradford staff are also involved. The study is funded by The Wellcome Trust.

If you have any questions about the project or just want to know more about the work we are conducting please contact the following study members on 01274 364474. We will attempt to answer any questions you may have.

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

We hope you are happy to take part.