

**We would like to ask you to take part in a research study. Before you decide, it is important for you to understand what the study is about, and what will happen to you if you take part. Please read this**

**leaflet carefully and ask us about anything that you do not understand.**

**What is the study for?**

Enbrel (Etanercept) and methotrexate are both medicines that are used to treat children with arthritis. We want to know more about how these drugs work, and if they have any good or bad effects. British Society for

Paediatric and Adolescent Rheumatology

doctors, nurses and others caring for children with arthritis have set up a patient list on a computer to collect information about how the drugs are working, and information about you and your arthritis. We would like to know how you are for the next five years or so.

**What information will we collect from you?**

The study will collect information about you, your arthritis, medical treatment and tests, how well you are and how you grow. All this information will come from the team you see for your normal hospital visits and you will not have to answer many (if any) questions from us on your own. This type of study is called an ‘observational study’ which means that we simply watch what happens to you -the study does not affect the treatment that you get from your doctor.

We may contact you through your doctor in the future as a follow-up to this study.

We may ask you about other research studies that you might be interested in through your doctor.

****We will also keep a very small amount of your blood to be looked at in our laboratories at the University of Manchester. We will get this when you have normal tests during your hospital visits, and if you cannot do this we will take a sample of your saliva (spit).

****You will be asked to provide an email address to receive information and updates about the study, and may be able to give answers to study questions online in the future. You do not have to provide an email address if you don’t want to.

**Why have I been chosen?**

You have been chosen because you have arthritis and are taking either Methotrexate or Etanercept.

**Do I have to take part?**

You do not have to take part if you do not want to.

If you decide not to take part it will not affect how your doctors treat you.

 If you **do** decide to take part, and your parents agree, you can sign a form to show this if you would like to.

You can change your mind at any time without saying why.

The information that we would collect about you will be kept secret. We will keep your name locked in the study office to help check information.

The results of the research will be written about in a medical journal. Your doctor will be able to tell you about how the research is going, and nobody outside the research team will know that your information is included in the study.

If you have any questions at all you can ask one of the people looking after you, or contact Professor Kimme Hyrich at the University of Manchester:

0161 275 5037

Kimme.hyrich@manchester.ac.uk

**Thank you for reading this information leaflet. If you do decide to take part in the study, please keep this information sheet so you can look at it in the future.**

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**Who is running and paying for the research?**

The register will be funded by the British Society for Rheumatology (BSR) and the Biologic Studies Group at the University of Manchester. The drug company Pfizer pays BSR for the study, but your doctor does not get any money.

BSPAR Etanercept Cohort Study

**Information for children (guide ages: 6-10)**

A Nurse or Doctor from the hospital will contact you and your parent by phone a few days after you get this leaflet to find out if you want to take part in the study. They will answer any questions you have. If you need more time to think about it, please let them know and they will be happy to call you again another day or talk about it at your next appointment.

If you want to take part, you can tell the nurse or doctor this on the phone. You and your parent will also be asked to sign a form to show that you agree

*NHS Letterhead here*