

**BSPAR Etanercept Cohort Study**

*NHS Letterhead here*

Version 4, 10/04/2018

**YOUNG PERSON INFORMATION SHEET (Guide age: 11—15)**

**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 usually have to answer 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 people - the study does not affect the treatment that you get from your doctor.

**Title of Project**: BSPAR Etanercept Cohort Study

**Name of Researcher**: Professor Kimme Hyrich

**IRAS: 42118**

 We would like you to take part in a research study.

 Please take time to read this leaflet carefully and discuss it with others if you wish.

 Ask us if anything is unclear, or if you would like more information.

 Take time to decide if you wish to take part.

 You will receive a telephone call in 2 week’s time to discuss the following information, and whether you wish to take part in the study or not.

If you do not want to discuss the study say so at once when we ring and we will end the phone call.

If the phone call is at an inconvenient time, we will arrange the call for a time that suits you.

If you feel that you wish to have more time to think about the information, please inform the health care professional when they call, and they will be happy to arrange another date and time with you, all will discuss it when you come to clinic

**Thanks for reading this!**

**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

**Why have you been chosen?**

You have been chosen because either you are taking etanercept or because you are taking methotrexate for Juvenile Idiopathic Arthritis.

We intend to invite as many children and young people as possible who are taking these drugs to take part.

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

Etanercept, an anti-tumour necrosis factor “biologic” drug and methotrexate are both treatments for severe Juvenile Idiopathic Arthritis (JIA) that have been tested in clinical trials. However, more information is needed on long term effects of biologic drugs; we especially need more information on the side effects they may produce as they have not been in use for very long.

**Are there any risks to me if I take part?**

The study will run alongside your routine arthritis care; it will not influence this process. Therefore, there are no foreseeable risks associated with this study. There would be no extra risk or additional discomfort to you when the blood sample is taken for the study, as this will be taken at a time when blood is also needed for routine purposes during a regular hospital visit.

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

Although there is no clinical benefit gained by participation in the research, the information

obtained from this study may result in changes in future treatment of patients with JIA.

**Why are you taking my blood, and what will you do with the sample?**

The research blood or saliva sample will be gifted to the Arthritis Research UK Centre for Musculoskeletal Research at the University of Manchester, where genetic material, such as DNA and plasma will be extracted. The exact genes to be studied cannot be identified now but will include ones we already know are important in childhood arthritis and ones discovered during the time the study is being undertaken. Some of the blood and saliva samples may be provided to other bona-fide researchers working in the field for future research of Juvenile Idiopathic Arthritis and response to treatment. You can refuse permission for this if you want and you can still take part in the study. No identifiable data would be stored directly with the sample, and the sample will be stored under secure conditions.

**What is genetics?**

Genetics is the study of genes. DNA is a molecule contained within nearly all your body’s cells and it contains genes within it. It is our genes that help determine certain characteristics, such as hair colour and gender as well as the likelihood that we will develop certain diseases. Genes vary between people and one of the purposes of this study is to investigate whether variation in genes affect how children with arthritis respond to treatment.

We will ask you to provide a small blood sample, which will be taken at a time when blood is also needed for routine purposes during a regular hospital visit. If you do not need a blood sample for routine clinical purposes, you will be asked to provide a saliva sample (we will get you to spit into a small cup).

We may contact you through your doctors about other studies you may be interested in, or regarding a later follow-up of this study.

We would want to flag you with national providers of health data – such as NHS Digital, which will provide the study with information about your health status.

**Will anyone know I have been involved with this research?**

All information used in the study is kept under secure conditions and is strictly confidential. Your GP will be informed that you are in the study.

**Thanks for reading this information leaflet. If you do decide to take part in the study, please return the consent form to us and we will send you a signed copy back.**

The research is funded by the British Society for Rheumatology (BSR), who receive money from the drug company Pfizer. Your doctor receives no payment in connection with this study. The study is coordinated by the University of Manchester. If you want to ask about anything please get in touch with the Chief Investigator Professor Kimme Hyrich (Kimme.hyrich@manchester.ac.uk)

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

The results of the study will be presented at scientific meetings and published in medical journals but no identifying information will be used.