PATIENT INFORMATION SHEET (SCOTLAND)
VERSION 2, May 2015

1. Study title

Childhood Arthritis Prospective Study (CAPS)

2. Invitation paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with relatives, friends and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

3. What is the purpose of the study?

Arthritis in children affects around one in a thousand children. In the majority of cases the cause is unknown. It is likely that the development of arthritis is related in part to the child's genetic make-up and in part to other factors such as infection or other illnesses. The arthritis may go away after some months or years or may persist into adult life. At the moment we cannot predict which children will recover and which children will have more long-term problems. The aim of the study is to identify factors that may be involved in the development of arthritis and to identify factors that may help in the prediction of the long- term outcome of the illness.

Better understanding of the cause of childhood arthritis may lead to the possibility of prevention of the illness in future. Better understanding of the course of the illness will help in choosing the best treatment for children in the future.

4. Why have I been chosen?

We are asking all children who have recently developed arthritis to take part in this study.

5. Do I have to take part?

You do not have to take part in this study. It is up to you to decide whether or not to take part. Your treatment will not be affected if you decide not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

6. What will happen to me if I take part?

(i) The study will begin as part of a normal visit to the Rheumatology Clinic. The

Hospital Consultant will ask patients and parents whether they are happy to take part in the study. If you agree then the consultant will send your name, address and telephone number to the Research Nurse. The Consultant will also provide details of your illness and treatment as well as the results of any blood test or X-rays that have been done as part of the hospital visit.

(ii) The nurse will complete a form about your medical history. You will be asked to complete some questionnaires about how the arthritis affects your daily activities, your moods and how it affects you. You will also be asked about any family history of arthritis and related conditions. Occasionally, these questions may be posed over the telephone or we may post the questionnaires to your home. Follow-up questionnaires will be sent to you around once per year, although these may become less frequent as the study progresses. At this stage we do not know how long in total we will want to collect this information from you but in the first instance we imagine this will be for at least 10 years.

(iii) Information regarding your health status will also be obtained from your medical case notes.

(iv) At some point we will ask you to provide a small blood sample (about one teaspoon). Blood tests are a necessary part of the management of arthritis in children. The research blood sample will be taken at a time when blood is also needed for routine purposes. Therefore there would be no additional discomfort and no extra risk to you. If you do not require a blood sample for routine clinical purposes you will be asked to provide a spit sample. The procedure will not cause you any discomfort. Samples will be sent to the Centre for Musculoskeletal Research Laboratories at the University of Manchester where genetic material (plasma/cells/DNA/RNA) will be extracted. This will be stored under secure conditions until the study is complete. The material will only be used for research into the genetics of childhood arthritis. 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 done.

(v) As part of routine clinical care it may be necessary for you to have some fluid removed from a joint and a joint injection. This is often done under general anaesthetic. The fluid removed is usually thrown away. This fluid may be sent to the Centre for Musculoskeletal Research laboratories for research purposes. A small (about 1-2 teaspoons) additional blood sample will be taken at the same time for research purposes and also sent to Centre for Musculoskeletal Research laboratories. Both of these samples will be used to try to identify which genes are causing the joint swelling.

(vi) The National Health Services Central Register (NHSCR) (or their equivalent) collects statistics on health outcomes across the United Kingdom in collaboration with the NHS. Examples of this data include information on any resident of the UK who dies and anybody who develops a cancer. Researchers can “flag” the names of participants involved in their research with the NHSCR such that in the rare event one of these health outcomes occurs, the researchers will be informed. This allows them to have almost 100% complete information on these rare outcomes. With your permission, your name would be “flagged” with the NHSCR. This will allow us to study very long-term outcomes, far into adulthood, in children who have or have had arthritis.

(vii)

Data linkage, the process of linking together two or more streams of data, allows

researchers to make use of routinely collected data (e.g. when a child is admitted to hospital) that benefits research. With your permission, we would apply to the National Health Service Central Register to link data from the CAPS study with your hospital data to provide a more detailed picture of these health outcomes.

7. What are the possible disadvantages and risks of taking part?

There is no risk associated with taking part in the study and the only inconvenience is the time given over to completing the questionnaires. As mentioned above, the research blood sample would be taken at the same time as blood was required for routine testing and so no additional risk would be involved.

8. What are the possible benefits of taking part?

The research may not have a direct benefit for you or your family. However, many families find it helpful to talk about the illness and the impact that it is having on the life of the family with someone who is independent (e.g. a Research Nurse).

9. Will my taking part in this study be kept confidential?

The patient's notes are kept confidential as usual at the hospital. Separate research records will be kept by the Research Nurse and only those involved in the study will have access to them. Since this study involves a number of Centres in the United Kingdom, information about you will be sent to the Centre for Musculoskeletal Research at The University of Manchester. Each participant will be given a code number so that they cannot be identified. All data will be stored on a secure database that can only be looked at by authorised individuals. The individual results from any genetic studies will not be provided to you, your family, the Consultant or any other organisation or individual. With your permission you GP will be notified of their participation in the study.

10. What will happen to the results of the research study?

The results of the study will be presented at scientific meeting and published in medical journals but, again, no identifying information will be given in these publications.

11. Who is organising and funding the research?

The research is being funded by the Arthritis Research UK and will be organised by the Arthritis Research UK Epidemiology Research Unit at Manchester University.

You consultant will not receive any payment for including and looking after any patients in the study.

12. Who has reviewed the study?

This study has been reviewed by the Northwest Multi Centre Research Ethics

Committee.

13. **Contact for Further Information**

If you have any questions about the study please discuss them with Prof. Wendy Thomson or Dr. Kimme Hyrich at the Centre for Musculoskeletal Research, University of Manchester. Telephone: 0161 275 5037/5040.

If you wish to take part in this study please complete the Consent Forms which you have been given and hand them back to your Consultant/Research Nurse or return to the Centre for Musculoskeletal Research by post.