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Centre Number: <centre number>

## Parent/Legal Representative Information Sheet

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### We invite you to provide consent for your child/relative's information to be used in a research study

The BOSS study is a research study lead by surgeons and scientists who are working to improve the treatment of children and young people who have rare bone diseases. This study is focusing on children affected by Slipped Epiphysis or Perthes' disease. This is a 'cohort study', which means that we follow your child's condition closely over the next 2 years, and into the future.

The study is the work of a large group of orthopaedic (bone) specialist doctors across the UK, with help from researchers from the University of Oxford & University of Liverpool.

Before you decide if you want to give your permission for your child/relative's information to be used in this study it is important for you to understand why the research is being done, and what it will involve.

Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish.

You are free to decide whether or not you wish for your child/relative's information to be used. Your decision will not affect the care your child/relative will receive.

### How to contact us

If you have any questions please contact:

Research Nurse – Name  
Telephone: **number**

Principle Investigator – Name  
Telephone: **number**

### Important things that you need to know

- Your child has been diagnosed with a rare hip disease (either Perthes' disease or Slipped Epiphysis).
- There is a lot that still isn't known about rare hip diseases in childhood.
- This is an observational study, which means we wish to closely monitor your child over the course of their treatment, without changing any part of the care given.
- Your child will be asked to complete some questions about pain, activities and feelings. These questions will be asked at the beginning of the study, and on several occasions up to two years from now.
- Your child's details (i.e. NHS number) will be kept securely to enable researchers to contact your child in the distant future to find out more about their hip condition.

## 1) Why are we doing this study?

There isn't a lot known about rare bone diseases in childhood. One of the big problems is that most hospitals may only see one or two children with a disease each year. We are trying to find all the children in the country with the same condition as your child/relative. By looking at everyone's care and results together, we can then improve our understanding about the best way to treat these diseases. This kind of study is one of the best ways of finding out.

This hospital is one of many that is taking part in this study across the country. The study will involve approximately 500 children and young people.

## 2) Will there be extra tests?

No. This study asks you and/or your child some extra questions, and makes use of the routine information that your doctor collects. No aspect of the treatment that your child will receive will be changed by taking part in this study.

## 3) What does the study involve?

The doctors and nurses will monitor your child/relative closely over the next 2 years with occasional questionnaires, and then into the future using national NHS healthcare databases. A summary of your child's/relative's routine medical records will be made available to the research team at Liverpool University. Information will be transferred to, and stored at, the Medicines for Children Clinical Trials Unit at The University of Liverpool, where it will be held securely.

With your consent, we will share your child's NHS number with NHS Digital. The information we share will be used by NHS Digital and other central UK NHS bodies in order to provide us with information about your child's health status in the future.

If you do not agree for your child/relative to be part of this study, this will not change the care they will receive. You can change your mind at any time and can contact the research team using the contact details on the first page of this sheet. The study results will be made available on the study website when the study is finished: [www.boss.surgery](http://www.boss.surgery)

## 4) Who is involved with the study?

The study is funded by the Department of Health and is the work of children's bone specialists across the UK, with research support from Oxford and Liverpool University. Alder Hey Children's NHS Foundation Trust and The University of Liverpool are the lead centres for the study and the day to day running of the study is being completed by the Medicines for Children Clinical Trials Unit (MC CTU), part of the University of Liverpool.

The research team is qualified to do this study because they have all the specialties and skills needed. The team has a lot of experience in caring for children and young people with these disease and are very active in health research. Parents and children with Perthes' disease and Slipped Epiphysis have been involved in the development, and are involved in the ongoing management of this study.

The study has been reviewed by a research ethics committee, who have agreed the study is being conducted in a correct and appropriate manner.

## 5) What if there is a problem?

If you have a concern about any aspect of the BOSS Study, you should ask to speak with the research team who will do their best to answer your questions <Insert PI/RN Tel no.>. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your child/relative's hospital.