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Parent/Guardian Information Sheet (for Wales)

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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/relative'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/relative 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/relative 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/relative'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/relative some extra questions, and makes use of the routine information that your doctor collects. No aspect of the treatment that your child/relative 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/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 Clinical Trials Research Centre (CTRC) at The University of Liverpool, where it will be held securely.

With your consent, we will share your child/relative's NHS number with NHS Wales Informatics Services. The information we share will be used by NHS Wales Informatics Services and other central UK NHS bodies in order to provide us with information about your child/relative'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

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 Clinical Trials Research Centre (CTRC), 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.

The University of Liverpool is the sponsor for this study based in the United Kingdom. We will be using information from your child/relative and their medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Liverpool will keep identifiable information about you for 20 years after the study has finished¹.

¹ This may be subject to change
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Your rights to access, change or move your child/relative's information are limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate. If you withdraw your child/relative from the study, we will keep the information about them that we have already obtained. To safeguard their rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your/their information at <http://boss.surgery/>.

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your child/relative's personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Our Data Protection Officer is Victoria Heath and you can contact them at LegalServices@liverpool.ac.uk.

Your NHS trust will collect information from you and your child/relative's medical records for this research study in accordance with our instructions.

Your NHS trust will use your child/relative's name, NHS number and contact details to contact you/them about the research study, and make sure that relevant information about the study is recorded for their care, and to oversee the quality of the study. Individuals from the University of Liverpool and regulatory organisations may look at your child/relative's medical and research records to check the accuracy of the research study. Your NHS trust will pass these details to the University of Liverpool along with the information collected from you and your child/relative's medical records. The only people in the University of Liverpool who will have access to information that identifies you/your child/relative will be people who need to contact you to ask you/your child/relative to complete a questionnaire, provide a summary of the findings at the end of the study (if you have registered your wish to receive this), or audit the data collection process. The people who analyse the information will not be able to identify you/your child/relative and will not be able to find out your/their name, NHS number or contact details.

Your NHS trust will keep identifiable information about you/your child/relative from this study for 15 years after the study has finished/ until documents are no longer needed.

University of Liverpool will collect information about your child/relative for research from NHS Wales Informatics Services and other central UK NHS bodies. This information will include their name, NHS number, contact details and health information, which is regarded as a special category of information. We will use this information to enable us to follow your child/relative up in the long-term, principally to identify if their hip needs to be replaced, by linking the information we hold to other national datasets detailing hip replacement data.

When you agree to take part in a research study, the information about your child/relative's health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in

this country or abroad. Your child/relative's information will only be used by organisations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](#).

Your child/relative's information could be used for research in any aspect of health or care, and could be combined with information about them from other sources held by researchers, the NHS or government.

Where this information could identify your child/relative, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you/your child/relative about future opportunities to participate in research. It will not be used to make decisions about future services available to your child/relative, such as insurance.

Where there is a risk that your child/relative can be identified, their data will only be used in research that has been independently reviewed by an ethics committee.

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.