The University of Texas Southwestern Medical Center at Dallas
Texas Scottish Rite Hospital for Children

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research: Multi-Center Prospective Cohort Study on Management of Legg-Calvé-Perthes Disease

Funding Agency/Sponsor: None

Study Principle Investigator: Harry K.W. Kim, MD

You may call the study doctor or research personnel during regular office hours at 214-559-7877. At other times, you may call them at 214-559-5000.

Note: If you are a parent or guardian of a minor and have been asked to read and sign this form, the "you" in this document refers to the minor.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?
This study is being done to help orthopaedic surgeons better understand and treat patients with Legg-Calvé-Perthes Disease (Perthes), also known as idiopathic femoral head osteonecrosis. We are creating a database to see how hips turn out in patients who have Perthes. (Idiopathic means arising spontaneously or from an obscure or unknown cause. Osteonecrosis is bone death resulting from poor blood supply to an area of bone.)

Perthes is a hip condition where children lose blood supply to the head of the femur or hip bone (sometimes referred to as the ball of the "ball-and-socket" joint). The reason this happens is not known. Many children who have Perthes heal the ball over the course of one to two years and do not have more hip problems. Some children, especially children who are older when the problem starts, do have problems with the healing and develop balls that are not round and do not stay matched to the socket.
Because Perthes is not very common, it is difficult for one doctor or hospital to collect enough cases to predict how patients' hips will turn out. This study will collect cases from many doctors and hospitals into one computer database. The researchers can then try to find out what factors on X-rays or magnetic resonance imaging (MRIs) help

predict poor outcomes. The participating doctors will still perform their usual treatments, which might include no specific treatment, keeping the weight off the hip with crutches or a walker, casting, or surgeries to release tendons or reshape the ball or socket of the hip. The research study will not direct the doctors to perform a certain type of treatment, but will keep track of what type of treatments patients had and how their hips turned out later. No treatment procedures will be done solely for research.

We are also interested in assessing the quality of life of patients with Perthes Disease using the *Patient Reported Outcomes Measurement Information System (PROMIS)* questionnaire. This survey has yet to be evaluated for use in the Perthes population. This survey will be administered to your child for a self assessment if he or she is aged 8 years or older. If your child is between the ages of 1 to 8 years, the questionnaire will be given to you and your child to complete as a proxy assessment. The results of this study will help orthopaedic surgeons in the future to determine which types of treatment for LCPD have the greatest effect on quality of life.

If you decide to complete the PROMIS questionnaires, you or your child have the option of filling out the online survey today during your clinic visit or taking the survey on a computer at home. The questionnaire will take about 15-20 minutes to complete. If you or your child would like to complete the questionnaire in clinic, a member of the research team will give you or your child access to the study website and will be available to answer any questions that arise during completion of the survey. If you or your child decides to complete the survey from a computer at home, you will be given written instructions to access the survey on any computer. A phone number will be available for you to call the research team if any questions come up when you or your child are completing the survey at home. All data collected in the questionnaire will be marked with a code identifier and will not be personally identifiable. You or your child has the option of not taking part in the PROMIS questionnaire part of the study if you are not comfortable with answering the questions.

Why am I being asked to take part in this research study?

You are being asked to take part in this study because either: (1) you are between the ages of 1 and 18 years old at time of presentation and have Legg-Calvé-Perthes disease, or(2) you are over the age of 11 years and have femoral head osteonecrosis.

Since idiopathic femoral head osteonecrosis (Perthes) is not often found in the age group over 11 years of age, we are studying any femoral head osteonecrosis cases in this age group.

How many people will take part in this study?

Up to 300 people will take part in this study at Texas Scottish Rite Hospital for Children.

This study also is taking place at a number of other medical facilities around the globe. There will be a total of up to 1500 people participating in this research study

throughout the United States and other countries.

What is involved in the study?

If you agree to be in this study, you will be asked to sign this consent form. Most of the procedures involved in the study are part of your standard medical care and you will be asked to complete questionnaires that are used solely for research purposes. Your doctor will send information about you and your past medical history, how long you have had hip symptoms, pictures of your X-rays and/or MRIs, and answers to questionnaires you fill out about how you are doing to a computer database. You will still have regular clinic visits with your doctor as part of your standard care that will include routine (standard medical care) X-rays or MRIs to follow the healing of the hip. You will have to spend some time (less than 30 minutes per visit) filling out questionnaires about how your hip feels.

How long can I expect to be in this study?
Five years after you are enrolled into the study or until you are skeletally mature (age 14 in girls and age 16 in boys).

If you are asked to participate only in the PROMIS portion of this study, your involvement in the study lasts only as long as required for you to complete the questionnaire, typically 15-20 minutes unless you opt to complete the questionnaire at home.

Whether or not you take part in this study is your choice. You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

You may be removed from the study without your consent if the sponsor ends the study, or if you are not following the study rules.

What are the risks of the study?
You should not experience any direct health risk due to participation in this study. You will receive routine (standard medical) care that includes X-rays and MRI. Additionally, your doctor will continue to treat your Perthes as usual. These treatments or procedures may have risks that your doctor will explain to you, but participating in the study does not change the risks.

Psychological Stress
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time.

Loss of Confidentiality
Any time information is collected, there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Other Risks
There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

What are the possible benefits of this study?
If you agree to take part in this study, there may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research.

We hope the information learned from this study will benefit others with Legg-Calvé-Perthes Disease in the future. Information gained from this research could lead to better ways to diagnose and treat Legg-Calvé-Perthes Disease.

What options are available if I decide not to take part in this research study?
This is not a treatment study. You do not have to be part of it to get treatment for your condition.

There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. Your doctor will still continue to treat you.

Will I be paid if I take part in this research study?
No. You will not be paid to take part in this research study. There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Will my insurance provider or I be charged for the costs of any part of this research study?
No. Neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas or Texas Scottish Rite Hospital for Children.

You retain your legal rights during your participation in this research.

Can I stop taking part in this research study?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern or Texas Scottish Rite Hospital for Children staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

Your doctor is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Will my information be kept confidential?
Medical information collected during this study and the results of any test or procedures that may affect your medical care may be included in your medical record. Tests or procedures ordered and resulted in the Epic system and/or TSRH Siemens Clinical Suites system may be included in your electronic health record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Representatives of government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people, and
- The UT Southwestern Institutional Review Board.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details

about how your information will be used for this research study, and who may see and/or get copies of your information.

The researchers will not, in any case, disclose information about you or your participation in this study unless it is included in the Authorization for Use and Disclosure of Protected Health Information for Research Purposes as stated above.

Whom do I call if I have questions or problems?

For questions about the study, contact Harry K.W. Kim, MD, at 214-559-7877 during regular business hours and at 214-559-5000 after hours and on weekends and holidays.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.
- You understand that a copy of this signed consent document, information about this study and the results of any test or procedure done may be included in your medical record and this information may be available to health care providers and authorized persons including your insurance company.

_____
Name of Participant (Printed)

_____ _____ _____AM / PM
Signature of Participant Date Time

_____
Legally Authorized Representative's Name (Printed)

_____ _____ _____AM / PM
Legally Authorized Representative's Signature Date Time

_____
Name of Person Obtaining Consent (Printed)

_____ _____ _____AM / PM
Signature of Person Obtaining Consent Date Time

ASSENT OF A MINOR:

I have discussed this research study with my parent or legal guardian and the researchers, and I agree to participate.

_____ _____ _____AM / PM
Participant's Signature (age 10 thorough 17) Date Time

The University of Texas Southwestern Medical Center at
Dallas Texas Scottish Rite Hospital for Children

Authorization for Use and Disclosure of Health Information for Research Purposes

NAME OF RESEARCH PARTICIPANT:_____

What is the purpose of this form?
This authorization describes how information about you and your health will be used and shared by the researcher(s) when you participate in the research study: "Multicenter Prospective Cohort Study on Current Treatments of Legg-Calve-Perthes Disease," a research database of prospectively identified patients with Legg-Calve-Perthes Disease ("Research Project"). Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and others (described in detail below) to have access to and share this information. If you have questions, please ask a member of the research team.

Who will be able to use or share my health information?
Texas Scottish Rite Hospital for Children may use or share your health information with other investigators ("Researchers") for the purpose of this research study.

Will my protected health information be shared with someone other than the Researchers? Yes, the Researchers may share your health information with others who may be working with the Researchers on the Research Project ("Recipients") for purposes directly related to the conduct of this research study or as required by law. These other people or entities include:

- The UT Southwestern Institutional Review Board (IRB). This is a group of people who are responsible for assuring that the rights of participants in research are respected. Members and staff of the IRB at UT Southwestern may review the records of your participation in this research. A representative of the IRB may contact you for information about your experience with this research. If you do not want to answer their questions you may refuse to do so.

- Collaborating Institutions: There will be other future research facilities who wil work with Texas Scottish Rite Hospital for Children on the Research Project.

- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

How will my health information be protected?
Whenever possible your health information will be kept confidential as required by law. Federal privacy laws may not apply to other institutions, companies or agencies collaborating with UT Southwestern on this research project. There is a risk that the Recipients could share your information with other without your permission. UT Southwestern cannot guarantee the confidentiality of your health information after it has been shared with the recipients.

Medical information collected during this study and the results of any test or procedure that may affect your medical record will be available to health care providers and authorized persons including your insurance company.

Why is my personal contact being used?
Your personal contact information is important for the UT Southwestern Medical Center research team to contact you during the study. However, your personal contact information will not be released without your permission.

What health information will be collected, used and shared (disclosed)?
The Researchers will collect:

- Age/Date of Birth
- Gender
- Ethnicity
- Height/weight/BMI
- Birth weight
- Date of first symptoms
- Date of diagnosis
- Date of radiographic studies
- Age at skeletal maturity
- Results of contrast-enhanced MR imaging
- PROMIS Questionnaire
- Date of first TSRHC Orthopaedic Clinic visit
- Dates of contrast-enhanced MRIs
- Clinical data
- Surgical data
- Family history
- History of maternal smoking
- Concomitant illnesses or disorders
- History of corticosteroid therapy
- History of trauma
- Results of radiographic studie

Will my health information be used in a research report?
Yes, the research team may fill out a research report. (This is sometimes called "a case report".) The research report will not include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care and a tracking code. The research report will also include information the research team collects for the study.

Will my health information be used for other purposes?
Yes, the Researchers and Recipients may use your health information to create research data that does not identify you. Research data that does not identify you may be used and shared by the Researchers and Recipients in a publication about the results of the Research Project or for other research purposes not related to the Research Project.

Do I have to sign this authorization?
No, this authorization is voluntary. Your health care providers will continue to provide you with healthcare services even if you choose not to sign this authorization. However, if you choose not to sign this authorization, you cannot take part in this Research Project.

How long will my permission last?
This authorization has no expiration date. You may cancel this authorization at any time. If you decide to cancel this authorization, you will no longer be able to take part in the Research Project. The Researchers may still use and share the health information that they have already collected before you canceled the authorization. To cancel this authorization, you must make this request in writing to: Harry K.W. Kim, MD, 2222 Welborn Street, Dallas, Texas 75219, 214-559-5000.

Will I receive a copy of this authorization?
Yes, a copy of this authorization will be provided to you.

Signatures:

By signing this document you are permitting UT Southwestern Medical Center to use and disclose health information about you for research purposes as described above.

_____ _____ _____
Signature of Research Participant Date AM/PM Time

For Legal Representatives of Research Participants (if applicable):

Printed Name of Legal Representative:

Relationship to Research Participant:_____

I certify that I have the legal authority under applicable law to make this Authorization on behalf of the Research Participant identified above. The basis for this legal authority is:

_____
(e.g., parent, legal guardian, person with legal power of attorney, etc.)

_____ _____ _____
Signature of Legal Representative Date AM/PM Time