



INFORMED CONSENT FORM

THE PROSPECTIVE NATIONWIDE STUDY OF PERTHES` DISEASE IN NORWAY

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Research coordinator: Johan Brevik

Name of Organization: Oslo University Hospital

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

INTRODUCTION AND PURPOSE

You have previously been treated for hip disease (Calvé-Leg-Perthes disease, CLP). This is a question for you to participate in a research study to investigate the results of the treatment you have received. The study is important to find out more about the results and any risk factors of importance to the long-term outcome of this disease. Responsible for the study is Oslo University Hospital HF, Rikshospitalet.

TYPE OF RESEARCH

The project consists of an examination, an X-ray examination of the hips and questionnaires on general health conditions and hip joint function. We will also use relevant information from your patient record at the institution responsible for your treatment as a child, as well as previous X-ray examinations.

CONFIDENTIALITY

It is possible that if others in the community are aware that you are participating in this research, they may ask you questions. We will not be sharing the identity of those participating in the research with anyone. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will not be identified by your name but by a number. Only the researchers will know what your number is and they will lock that information up with a lock and key.

REIMBURSEMENT

We will reimburse for your travel expenses to the clinic. You will not be given any other money or gifts to take part in this research.

POSSIBLE BENEFITS

Participation in the study involves a thorough examination of your hips, both with testing and X-ray examination. This will give you as a participant a better insight into the development of the hip after previously undergone childhood illness. It is possible to identify potential risk factors for the development of hip wear and there are medical professionals present who can give advice and information if signs of wear should be discovered.

The benefits of participating in this study are that you help us learn more about the long-term development and function of the hip after undergoing childhood disease. It allows future patients to undergo the same treatment as you can.

POSSIBLE DISADVANTAGES

The disadvantage of participating is that 2 X-rays must be taken during examination, but the radiation dose at each examination is very low, roughly equivalent to flying back Los Angeles USA. It is not expected that the functional testing is painful.

VOLUNTARY PARTICIPATION

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. You may change your mind later and stop participating even if you agreed earlier.

Please contact the coordinator of the project for further information: Johan Brevik email: jobrev@ous-hf.no or telephone 23071748.

RIGHT TO REFUSE OR TO WITHDRAW

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

CONTACT

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: Johan Brevik email: jobrev@ous-hf.no or telephone 23071748.

CERTIFICATE OF CONSENT

I have been invited to participate in research of Perthes hip disease. I understand that it will involve a physical and x-ray examination. I have been informed that the risks are minimal and may include only a minor exposure of x-rays. I am aware that there may be no benefit to me personally and that I will not be compensated beyond travel expenses. I have been provided with the name of a researcher who can be easily contacted using the number and address I was given for that person.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year