UNIVERSITY OF ALBERTA

PARENT INFORMATION SHEET & CONSENT

Title: Prospective assessment of developmental hip dysplasia in infants by 3D ultrasound.
Principal Investigator: Dr. Jacob Jaremko
Study Team Phone: (780) 407-7923 (Carol Rae, Administrative Assistant)

We are asking you to consider taking part in a research study. Before you make a decision one of the researchers will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. If you agree to join the study, you will be asked to sign this form and you will be given a copy for your records.

What is the reason for doing this study? This is a research study using a type of imaging called ultrasound, which uses sound waves to take pictures inside the body. In this study we will be scanning hip joints in infants. Because current tools to screen for abnormal hips in infants are inaccurate or too costly, infants are not routinely screened in Canada for hip dysplasia. Because of this some children with abnormal hips are not diagnosed until later in life, when treatment is much more difficult, while others whose hips are actually normal go through months of stressful and unnecessary treatment. Our goal is to see whether we can use modern 3-dimensional (3D) ultrasound technology with artificial intelligence to improve on current methods for diagnosing hip dysplasia. In hip dysplasia, the ball-and-socket joint does not develop normally, which may make the hip unstable and can lead to early arthritis.

You are being asked to take part in this research study because your child is between 0 and 1 years old. Your child's data will be added to that of thousands of other children in an international multi-centre study led by this University of Alberta study team.

What will happen in the study? If you agree for your child to participate in this study, our team will perform an ultrasound of your child's hips. The images will be evaluated by an artificial intelligence routine we are developing, supervised by an expert radiologist, which will predict whether the hips appear normal or potentially dysplastic. We will tell your doctor these results. If the hips appear abnormal we will recommend that you take your child for further assessment at an orthopedic clinic specializing in hips, but whatever the test results are, it will be up to you and your doctor whether you do this.

Will there be any risks? Ultrasound scans have no known risks. We do not foresee any physiological, psychological, social, legal or financial risks that might result from participating in the research.

Will there be any benefits?
We do not realistically expect any direct benefit from this study for your child. However, this project has the potential to benefit children worldwide in the future.

Do I have to take part in the study?

You and/or your child are free to choose not to have your child participate, and can withdraw from this study at any time, without affecting anything you are entitled to. If you choose not to participate or if you withdraw, it will not harm your child's relationship with his/her own doctors or affect his/her clinical care in any way. If your child is withdrawn from the study, any data acquired up to that time will still be used anonymously in analysis.

Disclosure of Research Findings

We will tell your doctor whether the ultrasound shows hips that appear normal or dysplastic. This is an experimental test and although we think it is accurate, we are not sure; you and your doctor can decide whether to take any action to confirm the test results.

In the unlikely event that a worrisome finding other than hip dysplasia is seen on your child's scan, a radiologist on our research team will discuss this with your doctor.

We also seek your consent to use your child's anonymous data to improve the test we have developed. The lead investigator in this study, Dr. Jaremko, is a co-founder of MEDO (http://medo.ai), a startup company which is developing computer software to allow hip ultrasound screening to be performed cost-effectively worldwide, especially in areas of need (rural or remote areas, developing countries). For this training, the computer only needs anonymous data (mainly your child's hip ultrasound images and the diagnosis). We will never use any data which could identify your child for any commercial purpose.

Conflict of Interest

As noted above, Dr. Jaremko is both the lead investigator in this study and a co-founder of a related startup company, MEDO, which exists to translate research findings into real clinical use. Dr. Jaremko is not paid by this company. MEDO has no control over our research study findings, their publication or presentation. There are no other real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors.

Data collection, Storage and Confidentiality:

During the study we will be collecting personal information about your child. The study team members and other personnel involved in running this study are committed to respecting your child's privacy. No data relating to this study that includes your child's name will be released outside of the Principal Investigator's office or published by the researchers. Sometimes, by law, we may have to release your child's information with his/her name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your child's health information is kept private.

The investigator/study staff may need to look at your child's personal health records from current or previous medical visits. Any personal health information that we get from these records will be only what is needed for the study.

The master file with your child's personal information will be stored in a secure encrypted hard drive stored in the Department of Radiology, University of Alberta, under the care of the Principal Investigator Dr. Jacob Jaremko in a locked office. Your child's information will receive

a unique code. Other researchers will only receive coded information, and will not be able to link the code to your child. Persons outside of the research team, such as our international collaborators, will not have access to any of the individually identifiable research data collected. Strict security safeguards are in place throughout Alberta Health Services to reduce the chance of misuse or unplanned release of information. The images taken will be saved in an anonymized format. This means that before saving, all the data that can identify your child will be deleted.

During research studies it is important that the data we get is accurate. For this reason your child's health data, including their name, maybe looked at by people from the University of Alberta auditors and members of the Research Ethics Board. By signing this consent form you are saying it is okay for the Principal Investigator/study staff to collect, use, disclose information about your child from their personal health records as described above.

After the study is done we will need to securely store your child's health data that was collected as part of the study. At the University of Alberta we have to keep the data stored for 5 years after the end of the study. If you leave the study, we will not collect new health information about your child, but we will need to keep the data that we already have.

Reimbursement of expenses: Your child's information will only be used for research and will not be sold. There are no financial incentives provided for participating in this study.

Compensation for Research Related Injury: In the unlikely event your child becomes ill or injured as a result of participating in this study, necessary medical treatment will be available at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

Questions & Contact Persons

If you have any questions about the research now or later, please contact the study administrative assistant (Carol: 780-407-7923). Dr. Jacob Jaremko can be paged through Diagnostic Imaging Reception at (780) 407-7132 and will answer any questions that you have about the research project.

If you have questions about your (your infant's) rights as a study participant you can contact the Research Ethics Office, at 780-492-2615. This office is independent of the study investigators.

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CONSENT FORM

Title of Research Study: Prospective assessment of developmental hip dysplasia in infants by 3D ultrasound - analysis of validity and reliability of a 3D ultrasound model by correlation with clinical and imaging findings.

Study Team: Carol Rae (Administrative Assistant) (780) 407-7923
Dr. Jacob Jaremko
(Page through Diagnostic Imaging Reception) (780) 407-7132

A copy of this consent form and information sheet will be given to you to keep for your records and future reference.

	Yes	No
Do you understand that your child has been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from the study at any time, without having to give a reason?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your records, including personally identifiable health information?	☐	☐

Who explained this study to you? _____

I agree to enrol my infant in this study.

_____
Child's Name

_____ _____ _____
Parent/Guardian Name Parent/Guardian Signature Date

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee_____ Date _____