

## **PARENTAL CONSENT FORM**

**Title of Study: Determining the immediate effect of Postural Advice using 3D non-invasive Ultrasound Imaging**

**Principal Investigator:** *Eric Parent, PT, Ph.D* 780 492 8889  
**Research/Study Coordinator:** *Kathleen Shearer* 780 993 6224

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### **Why is your child being asked to take part in this research study?**

You child is invited to participate because they have scoliosis. The goal of this study is to test the spine correction possible with different postural recommendations. This study will help understand which postural recommendations lead to better spine correction. We will test which instructions lead to the best spine correction.

We will recruit 35 participants in this study. This study is in addition to standard care.

Before you make a decision, a researcher will go over this form with you. Please ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

### **What is the reason for doing the study?**

We have a poor understanding of how different posture recommendations affect the spine.

The goal of this project is to better understand how postural recommendations influence the spine. We will determine the amount of correction in the curve angles and vertebra rotation observed in different positions.

This study will use safe and non-invasive ultrasound imaging testing strategy developed by our team to assess the 3D orientation of the whole spine.

### **What will your child be asked to do?**

Your child will attend a single visit to the Scoliosis Ultrasound Imaging lab in the University of Alberta Hospital. This exam will last approximately 1.5 hour. We will begin by fully explaining the study and signing the consent document. Your child will then change into comfortable exercise shorts or pants and a hospital gown with the back open. Your child's spine will be scanned 11 times as listed below. For each scan, the examiners will apply some ultrasound gel on the spine and be given instructions from a therapist on how to maintain the position. We

will calibrate the ultrasound imager by touching the base of the neck and the lower end of the spine. We will then scan the full spine in about 15-30 seconds. The scan consists of sliding a probe over the skin from the neck down to the level where the spine meets with the base of the hips. During the scans your child will breathe normally. In between each scan your child will wait a few minutes while we save the images. Your child will feel a gentle pressure from the probe sliding over the skin.

The scanning positions are:

#1 Normal standing

#2 Standing while leaning opposite to your major curve

#3 Natural sitting

#4 Natural sitting with arms supported on a desk

#5 Sitting leaning opposite to the major curve supported on arms crossed on the desk

#6 and #7 Sitting with crossed legs each way.

#8 Sitting in the lotus position (both legs crossed)

#9, 10, 11 Carrying bags with different load positions (both shoulders, left and right).

All the tests in this study are done for research only.

### **What are the risks and discomforts?**

The test procedures are non-invasive. There are no known short and long term risks associated with the use of ultrasound imaging. In very rare cases, a participant may feel light headed or dizzy during testing. In this situation, we will pause the session and take a break until your child feels comfortable enough to proceed, if they wish to do so. We will actively communicate with your child during the session to ensure they are feeling well and safe. Participation will not affect your child's treatment. New positions may produce some muscle soreness like any exercise after a period without training. This is normal. The best care is to remain active and continue normal activities. Your child may feel fatigue from doing the testing and they can ask for a rest at any time. It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to a study participant. If anything warrants attention the appropriate procedures will be followed.

### **What are the benefits to your child?**

We will know which postural advice lead to the best spine correction for your child. However, your child may not get any immediate benefit from being in this research study.

This study may help other people with scoliosis in the future. We will find out which postural advice best correct scoliosis. We will learn which instructions lead to the best correction. This will help refine postural advice given to patients in the future.

### **Does your child have to take part in the study?**

Being in this study is your child's choice. Participation is completely voluntary at all points during the study. If your child decides to be in the study, they can change their mind and stop being in the study at any time. It will in no way affect the care that your child is entitled to. During the study your child can ask to stop at any time.

**Will your child be paid for their participation in the research?**

A compensation of \$20 will be provided to compensate your child for the time, the travel, and parking expenses.

**Will your child's information be kept private?**

During the study we will be collecting data about your child. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your child's name will be released outside of the researcher's office or published by the researchers. Sometimes, by law, we may have to release your child's information with your child's name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your child's information is kept private.

During research studies, it is important that the data we get is accurate. For this reason, your child's health data, including your child's name, may be looked at by people from the University of Alberta and the Health Research Ethics Board.

After the study is done, we will still need to securely store your child's health data that was collected as part of the study. At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the study.

If your child leaves the study, we will not collect new health information about your child, but we may need to keep the data that we have already collected.

**What if I or my child have questions?**

If you have any questions about the research now or later, please contact **Dr Eric Parent 780 499-8889** or **Kathleen Shearer at 780 993 6224**. If you have any questions regarding your child's rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office has no affiliation with the study investigators.

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	<u>Yes</u>	<u>No</u>
Do you understand that your child has been asked to be in a research study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you read and received a copy of the attached Information Sheet?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand the benefits and risks involved in taking part in this research study?	<input type="checkbox"/>	<input type="checkbox"/>
Have you had an opportunity to ask questions and discuss this study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that your child is free to leave the study at any time, without having to give a reason and without affecting their future care?	<input type="checkbox"/>	<input type="checkbox"/>
Has the issue of confidentiality and privacy been explained to you?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand who will have access to your child's study records?	<input type="checkbox"/>	<input type="checkbox"/>
Who explained this study to you? _____		
I agree for my child to take part in this study:		
Signature of Research Participant's Parent _____		
(Printed Name) _____		
Date: _____		
I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.		
<i>This should be signed by the person who is conducting the informed consent discussion (if that is not the Investigator – the person that obtained the consent needs to sign here)</i>		
Signature of Investigator or Designee _____		Date _____
<b>THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT</b>		