

## **PARTICIPANT CONSENT FORM: Adults with scoliosis**

**Title of Study: Body structure and capacity evaluations of adults with scoliosis**

**Principal Investigator:** Eric Parent 780 492 8889

**Research/Study Coordinator:** Kathleen Shearer 780 993 6224

---

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

You are being asked to be in this study because you are an adult with scoliosis. The aim of this study is to evaluate what problems adults with scoliosis have compared to adults without scoliosis. It will help us better understand adult scoliosis and treat it better.

There are many recommendations on how to do a physical exam in adolescents with scoliosis and on how to assess a patient with low back pain. The assessment of adults with scoliosis is not described as well. This is why we would like to evaluate your condition combining techniques used in adolescent scoliosis and in low back pain. The exam that we want to use is similar to a standard physiotherapy exam but a bit longer.

The study will take place only in Edmonton and we expect to recruit 108 participants.

Before you make a decision one of the researchers 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 want to assess the problems that adults with scoliosis can have compared with participants of the same age who don't have a scoliosis. We hope to determine the problems that adults with scoliosis suffer from. This info will help plan future research and treatments.

### **What will I be asked to do?**

There are two parts to the assessment: a physical exam and the completion of online questionnaires that you can do at home. First, you will complete questionnaires on a computer. The questionnaires will take about 45 minutes. If you prefer a paper copy please ask for one. These are standard questionnaires that are commonly used in clinics to describe your pain, your treatment history, your quality of life and your function. We will also ask about your

feelings about activity and work. We will test how you feel about your appearance. We will record your activity level and your ability to work.

The physical exam will take about 1h15. It is a standard physiotherapy exam including tests in standing, lying and sitting. During the physical exam, the physical therapist will record: your back and leg range of motion; how your pain changes with repeated movements, the strength of your leg muscles and back, the sensation over your legs, if pressure or movements cause pain in your hip, pelvis and back. We will also take some photos to measure your posture. We will be video recording this exam so that a second examiner can review the tests.

We will access your Dr's file to verify your diagnosis and obtain your most recent spine radiographs. With your consent we will store the study information in a secure data repository to facilitate future research without your name or other identifiers.

#### Covid-19 procedures

Due to the nature of this study, the ability to maintain 2m or more of physical distance is not possible. As such, all visits will be conducted with several additional measures in place. Prior to arriving at the lab, both researchers and research participants will need to pass the Covid-19 screening tool provided by the Government of Alberta and Alberta Health Services. Participants will be asked to wash their hands prior to entering the lab, and hand sanitizer will be available in the lab itself. Researchers will be wearing masks, face shields, gloves and gowns for the duration of the visit where physical distancing measures cannot be maintained. Participants will need to wear a mask throughout the entirety of the visit. The research lab and all equipment will be cleaned and disinfected regularly after patient visits.

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

There is a low probability of minor discomforts. It is possible that the physical exam or the questionnaires make you tired (about 2 hours in total). To limit this, we offer that you complete the questionnaires at home at your own pace. You can also ask for a break or stop at any time during the exam. To understand what causes your pain, some test may produce your usual pain. The examiner will try a gentle test before applying more force if necessary. You may also be slightly sore in the 2-3 days following the exam. This is similar to being sore after trying a new activity. Soreness disappears quickly and the best way to treat it is continue your activities.

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 we find out anything new during the course of this research which may change your willingness to be in the study, we will tell you about these findings.

**Covid-19:** You will have an increased risk to Covid-19 as it will not be possible to maintain 2 metres or more of physical distancing throughout your appointment. We have put in place

6-110 Clinical Sciences Building  
Edmonton, Alberta, Canada T6G 2G3  
Tel: 780.492.1226  
Fax: 780.492.9948

several protocols as mandated by the Government of Alberta and the University of Alberta to help keep you safe during the physical exam.

**What are the benefits to me?**

Participants with scoliosis may have some indirect benefits because the result of the study could help them and their therapists better understand their condition. However, you may not get any benefit from being in this research study.

**Do I have to take part in the study?**

Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect the care that you are entitled to." You do not have to answer any questions that they are not comfortable with. If you choose to drop out of the study, simply tell the evaluator. You can ask that your data be removed from the study up to the time when we complete the data analysis.

**Will I be paid to be in the research?**

You will not be paid to be in the study. You will be able to use a free parking spot during your visit to the lab.

**Will my information be kept private?**

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

*The investigator or their study staff will need to look at your personal health records or at those kept by other health care providers that you may have seen in the past. We will get a copy of your most recent spine radiographs. To find this radiograph we will need your name, and hospital ID number. Any personal health information that we get from these records will be only what is needed for the study.*

*During research studies it is important that the data we get is accurate. For this reason your health data, including your name, may be looked at by people from the University of Alberta and the Health Research Ethics board. By signing this consent form you are saying it is okay for the study team to collect, use and disclose information about you from your personal health records as described above.*

6-110 Clinical Sciences Building  
Edmonton, Alberta, Canada T6G 2G3  
Tel: 780.492.1226  
Fax: 780.492.9948

*After the study is done, we will still need to securely store your 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 you leave the study, we will not collect new health information about you, but we may need to keep the data that we have already collected.*

**What if I have questions?**

If you have any questions about the research now or later, please contact **Dr Eric Parent 780 492 8889**. If you have any questions regarding your 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.

This study is not funded by a sponsor. To our knowledge no conflict of interest exist.

**CONSENT****Title of Study: Body structure and capacity evaluations of adults with scoliosis****Principal Investigator:****Eric Parent****Phone Number(s): 780 492 8889****Study Coordinator:****Kathleen Shearer****Phone Number(s): 780 248 2064**

	<u>Yes</u>	<u>No</u>
Do you understand that you have 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 leave the study at any time, without having to give a reason and without affecting your future medical care?		
Has the issue of confidentiality been explained to you?		
Do you understand who will have access to your study records, including personally identifiable health information?		
Do you understand that we will taking photograph for measuring your body structure when you agree to participate the study?	<input type="checkbox"/>	<input type="checkbox"/>
<b>Future Contact</b>		
Do you agree to be contacted for follow-up or to facilitate future research?		
Who explained this study to you? _____		
I agree to take part in this study:		
Signature of Research Participant _____		
(Printed Name) _____		
Date: _____		
Signature of Investigator or Designee _____		
Date _____		

**THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT**