

# INFORMED CONSENT

**TITLE OF STUDY:** Evaluation of segmental lumbar spinal motion and physiological responses following common spinal mobilization techniques

You are being asked to participate in this research study. Your participation is voluntary and if at any point you decide to discontinue participation you are permitted to do so. Please read the following information before agreeing to participate. A researcher from the list below will be available to go through the information with you and answer any questions that you may have.

**RESEARCH TEAM:** Department of Physical Therapy, Winston-Salem State University

Principal Investigator: Dr. Nathan Savage, PhD, DPT [savagenj@wssu.edu](mailto:savagenj@wssu.edu)  
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**STUDY LOCATION:** Winston-Salem State University, F.L. Atkins Building, 3<sup>rd</sup> floor

**PURPOSE OF STUDY:** Evaluate how the joints in your lower back and your nerves respond to commonly used manual therapy techniques applied to your lower back using ultrasound imaging and neurophysiologic measurements.

## STUDY PARTICIPANTS:

Inclusion Criteria:

1. Age  $\geq 18$  years old
2. BMI  $\leq 27$  kg/m<sup>2</sup>
3. No current lower back pain or known pathology in the lower back
4. Be able to follow basic verbal or written instructions
5. Be able to lie on stomach and assume child's pose position (rocking onto heels from hands and knees)
6. Be able to stand independently

Exclusion Criteria:

1. Previous trauma or surgery involving the lumbar spine (eg, vertebral fracture, disc herniation, discectomy, lumbar joint fusion, etc)
2. Injection procedure in the lumbar spine in the past month

**TIME COMMITMENT:** You will participate in one (1) phone call/conversation lasting approximately 5 minutes to screen for eligibility and attend one (1) testing session lasting approximately 30 minutes.

**STUDY PROCEDURES:** Upon arrival for testing, you will complete screening questions. A researcher will then review your paperwork for completeness and accuracy, explain all the study-related procedures to you, answer any questions you have about participation, and obtain your written informed consent. For the purposes of data collection, you will then be asked to expose your lower back region.

Testing will involve the following examination procedures: 1) measurement of height and weight; 2) evaluation of forward and backward bending in standing; 3) ultrasound imaging of your lower back joints while lying flat on your stomach (back in neutral), while propped on elbows (arching your back), and in the child's pose position (rounding your back with bent knees, pressing your bottom to your heels) at baseline, following joint mobilization technique, and after rest; 4) tibial H-reflexes which involve a mild to moderate electrical stimulation behind your knee and recording from your calf muscle using a surface electrode at baseline, during joint mobilization technique, following joint mobilization technique, and following rest.

**STUDY-RELATED RISKS:** This study involves no more than minimal risk. A force will be applied to your spine and there is a potential for soft tissues soreness that could last a day or two after the study. Applied forces will not exceed the forces and risks of day-to-day life. There are no known harms, discomforts, or side effects associated with the use of ultrasound imaging or any other procedures used in this study beyond those you encounter during your normal daily activity. If changes are made to the study protocol resulting in potential for additional risks or discomforts, you will be informed in advance and given the opportunity to reconsider your study participation.

**STUDY-RELATED BENEFITS:** There is no direct benefit to you for participating in this study. However, the information gathered during this study will help contribute to the body of physical therapy research and may provide benefits to society and the practice of physical therapy generally.

**ALTERNATIVES TO STUDY PARTICIPATION:** None

**COMPENSATION, COSTS, AND REIMBURSEMENT:** None

**WITHDRAWAL OR TERMINATION FROM STUDY AND CONSEQUENCES:** You are free to withdraw from this study at any time. If you decide to withdraw from this study, you should notify the research team immediately. The research team may also end your participation if you do not follow instructions or if your safety or welfare are at risk.

**CONFIDENTIALITY:** All personal information will be linked to a de-identified study ID and stored in a password protected file. All the ultrasound images obtained during the study will be labeled and saved under your unique study ID.

**DATA STORAGE:** All hard copy data will be stored in a secure location in the Department of Physical Therapy, Winston-Salem State University. All electronic data will be stored on a secure computer and server with password protection.

**DATA ACCESS:** Only the research team will access your study records to preserve confidentiality. Research records provided to authorized non-university entities will not contain identifiable information about you. Publications and/or presentations that result from this study will not include identifiable information about you.

**DATA RETENTION:** Data will be retained for the foreseeable future with no plans for destruction.

**QUESTIONS:** If you have any comments, concerns, or questions regarding this research study please contact any member of the research team listed above. If you are unable to reach a member of the research team listed at the top of the form and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact Winston-Salem State University Institutional Review Board via the Compliance Officer in the Office of Sponsored Programs and Research at (336) 750-2982, by e-mail at khaniu@wssu.edu or in person at 601 Martin Luther King Jr. Drive, Winston-Salem, North Carolina 27110.

**CONSENT STATEMENT:** You should not sign this form unless you have read and understood the above information related to Informed Consent for study participation. Your participation is voluntary. You may refuse to answer any question or discontinue your involvement in this study at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with the Department of Physical Therapy or Winston-Salem State University. Your signature below indicates that you have read the information in this consent form and have resolved any questions you may have had about study participation.

I agree to participate in the study described above.

**Participant signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Printed name of participant:** \_\_\_\_\_

**Researcher signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Printed name of researcher:** \_\_\_\_\_