Consent and Authorization Document

BACKGROUND

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you volunteer to take part in this research study. We are conducting this study to better understand how spinal manipulation, dry needling, and exercise affects people with back pain and how we can improve these treatments. The purpose of this experiment is to determine how the combination of spinal manipulation and dry needling can reduce pain in the back and help back muscles function better when followed by a home exercise program. We are also examining what exercises can be added to spinal manipulation and dry needling to make them more effective.

We are inviting you to take part in this research study because you have low back pain. You are not eligible to take part in this research study if you have had back surgery in the past, if you know you are pregnant, or if you are currently receiving treatment for your back pain from a physical therapist, chiropractor, massage therapist, or other type of medical provider. Also, a researcher will evaluate your back and if you have any signs of a problem with the nerves in your back (i.e., "sciatica") or any indication that your back pain may be due to a problem such as an infection, fracture or cancer, you will not be eligible to participate.

STUDY PROCEDURES

Initial screening questions will be completed by phone and you will be asked to complete a questionnaire to help determine the extent of your low back pain. Data collected from the survey may be used as part of the research study. If you decide to participate in this study, you will be asked to attend four sessions within a two-week treatment period. These sessions will occur 2-3 days apart. During the first session you will receive an initial evaluation; this will be followed by assignment into one of three treatment groups consisting of spinal manipulation, dry needling, or a combination of dry needling and spinal manipulation treatment. After evaluation and assignment, treatment will be performed during the first visit. The subsequent second, third, and fourth sessions will include treatment dependent on the assigned therapy group. Each of these sessions will last about 30 minutes.

At the initial assessment session you will be randomly assign to one of the three treatment groups. Randomization means that patients are put into groups by random chance. This means a computer will decide what treatment you get throughout the study, not the study investigators. There are three possible treatment groups that you might be randomized to consisting of spinal manipulation, dry needling, or a combination of spinal manipulation and dry needling. All groups will be receiving treatment followed by an exercise period. Each session will last about 30 minutes. The total treatment period for this study will last 4 weeks. We will evaluate you several times throughout the study at initial assessment, following the second and fourth treatments, and at the end of the 4 weeks. The diagram on the next page shows the flow of the study from enrollment to the final assessment and further lists the different assessments and questionnaires that will be performed throughout the course of the 4 weeks. More details of the treatment options are also described below.

Week 1		Week 2		Weeks 3 & 4	
Enrollment-Randomization Baseline Assessment With Measures & Treatment 1	Treatment 2 Measures: ODI NPRS	Treatment 3	Treatment 4 Measures: ODI NPRS Ultrasound	Home Exercise Program	Home Exercise Program End of Week 4: Final Assessment

Study Examination Procedures
If you agree to participate in this study, at your first session you will receive an examination that consists of you completing several questionnaires about your general medical history and how back pain affects your activities, and then you will receive a physical examination to assess your back muscle function with ultrasound. The questionnaires will take approximately 10 minutes to complete, and the physical examination will take approximately an additional 20 minutes to complete. The examination procedures will check to be certain that you are eligible to participate in the study, and determine your level of pain and function before starting any treatment. These examination procedures will be repeated at the end of week 2 and at the end of week 4.

Ultrasound Measurement Procedures
As a part of each examination, we will use an ultrasound machine to measure the function of your deep hip and back muscles. Ultrasound is a machine that transmits sound waves through the body and records the echoes as the sound waves move through different structures in the body. The echoes are transformed into images that can be viewed on a television screen. During the ultrasound measurements you will be asked to lie on your stomach or your side. A liquid gel will be placed on your skin to help transmit the sound waves. The ultrasound device will then be placed on your skin and you will be asked to perform three simple tasks while ultrasound measurements are taken. While lying on your side you will be asked to lift the leg on top off the table momentarily. While lying on your stomach you will be asked to lift one or both arms off the table.

Study Treatment Procedures

Spinal Manipulation
During the first four treatments you may receive a spinal manipulation treatment ("cracking your back"). The manipulation treatment will be performed by having you lay on your back or your side. A researcher will gently bend and rotate your body. You may feel and/or hear a "pop" during the manipulation procedure. The researchers have had extensive training in this form of treatment and use it routinely in their practice. You may also discontinue the treatment if you feel discomfort at any time.

Dry Needling
Dry needling utilizes small acupuncture needles inserted into areas of muscle dysfunction to reduce pain, decrease muscular trigger points, and facilitate increased muscle function. It is common to feel

some minor discomfort once the needles are placed in the form a dull ache, minor cramp, or minor sharp pain, with these discomforts steadily dropping the longer the needles are in place. It is also common to not feel any of the needles at all for the entirety of the treatment. A total of six needles with be places in specific areas on the back and remain in place for 10 minutes. During this time it is advised to remain relaxed and minimize movement of the low back. Upon completion of the 10 minutes the needles will be removed and discarded. The researchers have had extensive training in this form of treatment and use it routinely in their practice. You may also discontinue the treatment if you feel discomfort at any time.

Back Muscle Strengthening Exercises
These exercises are designed to improve the strength of the muscles around your back. The exercises involve lying on your back or side or being on all fours and contracting different muscles around your back. You will be given a copy of the exercises with pictures and instructions for the number of times the exercises are to be completed at home.

RISKS
The risks associated with participation in this study are minimal. You may experience muscle soreness in your trunk, arms, or legs from the examination. Based on our experience this type of soreness is common meaning that it occurs in 1% to 25% of participants. There is also a chance that the study treatment may be ineffective or could exacerbate your back pain. We have attempted to minimize this risk by having licensed healthcare professionals perform all study procedures and by ensuring that all participating healthcare providers have been thoroughly trained in the procedures to be used in this study. There are no known risks from the ultrasound measurements and it has been found safe to use over the abdominal region of pregnant women. Furthermore, there is a minimal risk of loss of confidentiality regarding collection of data and record information. All research information about you will be handled in a confidential (private) manner consistent with other health-related medical records.

UNFORESEEABLE RISKS
In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS
We cannot promise any benefits from your being in the study. You may benefit from participation by receiving spinal manipulation, dry needling, and exercises for your back. We hope that the treatments will help your back pain. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with low back pain better.

ALTERNATIVE PROCEDURES
If you decide not to take part in this study, there are a few alternative treatments or procedures available. You could be referred to physical therapy or a chiropractor and receive manual therapy, heat and/or cold therapy, ultrasound (deep heat), electrical stimulation, or different exercises for your low back pain. Alternatively you could pursue specialty physician care, which may include the use of injections, acupuncture, surgical consultation, and/or other treatments for your back.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact Dr. Julie Fritz at (801) 587-2237. If you feel you have been injured as a result of participation, please call Dr. Julie Fritz at (801) 587-2237**.**

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah Hospital, as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. If you decide not to participate there are no penalties and your health care will not be affected. If you decide to participate, you may discontinue participation at any time without any penalty. If you want to stop being in this study, please let the researchers know.

COSTS AND COMPENSATION TO PARTICIPANTS

There will be no cost to you for participation in this study. You will not be charged, nor will your insurance company be charged, for any test or visit that is completed for this study. You will not be compensated for participation in this research. However, you are guaranteed treatment free of charge for your low back pain in the form of exercise coupled with dry needling, spinal manipulation, or a combination of dry needling and spinal manipulation. This treatment is valued at $600-$800 compared to typical self-pay costs.

NUMBER OF PARTICIPANTS

We expect to enroll 99 participants at the University of Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address and email address
- Related medical information about you like your medical history, current and past medications or therapies for your back, and information from physical examinations such as spine stiffness and muscle function measures.
- All tests and procedures that will be done in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  - Members of the research team
  - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights;
- If we share your identifying information with groups outside of the University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form. If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?
You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date