Participant Name: _____ Date:_____

Title of Study: The assessment of lower back mechanical behavior and spinal loads in veterans with non-specific low back pain: a feasibility study

Principal Investigator: Babak Bazrgari_____ VA Facility: Lexington, KY_

**WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?**
You are being invited to take part in a research study. This study is about the relationship between low back pain experience and biomechanics of lower back. Biomechanics is the study of mechanical laws relating to movement or structure of living organisms. It is being funded by the Department of Veterans Affairs. By doing this study, we hope to learn about the role of lower back biomechanics in an individuals experience of low back pain. This initial information is to give you key information to help you decide whether to participate. We have included detailed information in the "RESEARCH DETAILS" section. Feel free to ask the research team questions at any time. Taking part in this study is completely voluntary.

**WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?**
The study will include one session during which we will ask you to complete a number of physical tests while we measure movement of your body parts, activity of your trunk muscles, and ground reaction force. We will also ask you to complete a number of surveys that are relevant to low back pain experience.

Your participation in this research will last about two and half hours.

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**
There is no direct benefit to you for participating in this study. A key reason you might want to volunteer is to help researchers gain information that may lead to helping other veterans in future. By doing this study, we hope to learn if there is any relationship between abnormalities in the mechanical and neuromuscular (nerves and muscle) behaviors of the human lower back and trunk and his/her experience of low back pain. Such knowledge will in turn help clinicians to offer better care for veterans suffereing from low back pain. For complete description of benefits, refer to Detailed Consent.

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**
Key reasons why you may not want to voulenteer are giving up 2-3 hours of your time, completing movements, being in/on a device and filling out questionnairs. Before starting the actual experiments, you will be required to answer a number of questions. Your answers will be then evaluated by members of our team to assure your eligibility based on some additional

criteria. If you do not meet these additional criteria, you'll be excluded from the study and will be given the reason why you should not take part in this study. For example, if you have had a joint replacement, the mechanical properties of your body are also influenced by the artificial joint. This can hinder us from reaching our goal, as we cannot separate such influence from age-related influences at present. As another example, if you have a pacemaker, you'll be excluded from the study as we do not yet know the level of risk involved for participants with such cases. For a complete description of risks, refer to the Detailed Consent.

There are no alternative treatments. The procedure being done are soley for the purpose of research. If you decide not to participate, you can always receive your normal standard of care.

**DO YOU HAVE TO TAKE PART IN THE STUDY?**
If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?**
The person in charge of the study is Babak Bazrgari, PhD of the Lexington VA Health Care System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his/her contact information is: Babak Bazrgari, Tel: 859-257-1379.

## RESEARCH DETAILS

**WHAT IS THE PURPOSE OF THIS STUDY?**
Biomechanics of human lower back is known to play a role in occurance of low back pain yet biomechanical assessment has not been implemented in treatment of low back pain. Over the past decade we have developed a set of biomechanical tools with the intention for use in clinics. This initial study will enable us to show the capability of our biomechanical tools in detection of abnormalities in lower back of patients with low back pain. With this research we hope to learn about the relationship between low back pain experience and biomechanics of lower back.

**HOW LONG WILL I BE IN THE STUDY?**
If you volunteer to take part in this study, you will be one of about 120 people to do so. This research study is expected to take approximately two years. Your individual participation in the project will take one session lasting about two and half hour.

**WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?**
All procedures are being done soley for research, the research team will oversee all procedures. Upon enrollment into the study, we will ask you to answer a set of 16 questions concerning your eligibility for study. Research team will review your answers and will determine whether you are eligible. If you were found ineligible, you will be given the reasons. Once your eligibility is

confirmed, you will be asked to completed questionares from the followings list that apply to you:

- A questionnaire related to general health status
- A questionnaire related to habitual phyiscla activity
- A questionnaire related to psychological factors at work and outside of work
- A questionnaire related to low back pain
- A questionnaire related to level of pain if you have low back pain at the time of data collection
- A questionnaire related to level of disability caused by low back pain
- A questionnaire related to fear-avoidance beliefs
- A questionnaire related to pain catastrophizing behvaiors
- A questionair related to pain self-efficacy behaviors

Within each of the above questionnaire that apply to you, you will be free to skip any questions that you would prefer not to answer.

We will then attach adhesive markers and sensors on the skin around your abdomen and back. These sensors include EMG electrodes to measure the activity of your muscles and position sensors to measure your body posture and movements. To obtain reliable muscle activity measurements, we will prepare the skin on the sites of EMG electrode attachment by removing hairs and cleaning with alcohol. After some preliminary warm up stretches, we will ask you to push and/or pull as hard as you can against a resistance. We will ask you to perform some basic daily activities like walking, sitting, standing, bending and moving a light object. We will ask you to stand in a device and stay relaxed while we raise your legs and measure your body resistance against such movement (see picture below). In the same device, we will also apply quick but small pushes or pulls to your trunk to record reflexes (see picture below). You can skip a test if it considerably aggravates your low back pain

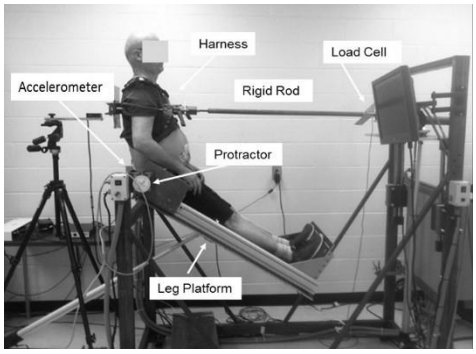


**Figure 1.** Experimental device.

If you choose to volunteer for this study, we ask you to respect the followings:

- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from

things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this research, as well as that of the other studies

**WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?**

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unexpected) risks also may occur.

Participants may feel unpleasant or uncomfortable answering some questions on the self-reported questionnaires. We will ensure participants that their answers are confidential and also inform them that they may choose not to answer any question.

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life. The risks of this study are minor. However, they include a potential for skin irritation due to the adhesives used in the tape and electrode markers. You may also feel some temporary muscle soreness such as might occur after exercising. Subjects participating in physical conditioning may experience muscle soreness and/or musculoskeletal injury associated with inherent risks of cardiovascular, strength training and therapeutic exercise. To minimize these risks you will be asked to warm-up before the tasks and tell us if you are aware of any history of skin-reaction to tape, history of musculoskeletal injury, or cardiovascular limitations. During prolonged testing, you may feel dizzy or light-headed, and there is a small risk that you could faint. To minimize these risks, you will be asked several times if you are experiencing such symptoms; if so, you will be asked to walk around or sit down as appropriate. In addition, hunger may exacerbate such risks, so you will be asked to not come to experimental sessions hungry, and small snacks will be made available should you become hungry.

**A. Common risks:**
Not applicable

***B.*** **Occasional:**
Not applicable

***C.*** **Rare:**
In 100 people completing our study protocol, 3 or fewer may have*:*

- *S*kin irritation due to the adhesives used in the tape and electrode markers
- Feel some temporary muscle soreness such as might occur after exercising
- feel dizzy, light-headed, or faint

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

Some people become uncomfortable at being asked questions about their low back pain; if, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

There will be no photographs, audio tapes, or video tapes made of you as part of this study.

**WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?**
There are no direct benefits to you from your taking part in this research study. However, the information we get from this study might help us treat future patients.

**WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?**
Not applicable

**HOW WILL MY PRIVATE INFORMATION BE PROTECTED?**
Taking part in this study will involve collecting private information about you. This information will be protected as follow:

- *Hard copies will be* locked in filing cabinets and electyronic information will be saved on computers protected with passwords.
- Only members of research team who are approved by the VA institutional review board will have access to these information.
- Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered.
- Any talks or papers about this study will not identify you.

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research.

While the study is being conducted you will not have access to your research related health records.

We will keep private all research records that identify you to the extent allowed by law. However, there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court. Also, we may be required to show information which identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as the Veteran Health Adminstration (i.e. funding agency).

**HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)**
There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, telephone number, date of birth or all elements of dates, and social security number.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Institutional Review Board, Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, **Babak Bazrgari** and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study.

**WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?**

You and/or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

*We will do our best to minimize any cost to you. Potential cost may include traveling cost and those due to time away from work.*

**Payment Offered for Participation:**
*You will receive $40 for taking part in this study. The payment will be in either in cash or via electronic funds transfer. The payment will be made by the Agent Cahsier Office.*

**WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?**
Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment in accordance with applicable federal regulations (38 CFR 17.85) at no cost to you.

The Lexington VAHCS will provide medical care if you get hurt or get sick as a result of taking part in this study. The necessary care must be provided in a VA medical facility unless an exception is granted. In cases of exceptions, the Lexington VAHCS Director may contract for such care. Exceptions include: situations where a VA facility is not capable of furnishing economical care, situations where a VA facility is not capable of furnishing the care or services required and situations involving a non-veteran research subject. Treatment for research-related injuries will be provided at no cost to you. However, this does not apply to treatment for injuries that result from noncompliance by a research subject with study procedures. If a research subject needs treatment in a medical emergency, the Lexington VAHCS may provide reasonable reimbursement for emergency treatment in a non-VA facility.

A co-payment from you may be required for medical care and services provided by the Lexington VAHCS that are not for research-related injuries.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Dr. Babak Bazrgari at 859-257-1379 and

AFTER HOURS:

Dr. Babak Bazrgari at 540-808-5743._____

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form

**DO I HAVE TO TAKE PART IN THE STUDY?**
Participation is voluntary; refusal to participate in the study involves no penalty or loss of benefits to which you are otherwise entitled. It is up to you to decide whether or not to take part in this study. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. If you decide to take part you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. If you don't take part or decide to

withdraw, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

There are no consequences if you decide to withdraw from the research. Note that the investigator may continue to review the data already collected for the study but will not collect further information.

**RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION**
We do not foresee any potential reason why the research team or investigator would terminate your participation in the study, however if any medical or safety issues arise, your participantion may be terminated without regards to your consent.

**WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?**
Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Babak Bazrgari, PhD at 859-257-1379. You can alternatively contact Dr. Theresa Wolfe at 859-233-4511, or at theres.wolfe@va.gov. Dr. Wolfe is a VA physician and a Co-investigator of this project.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Lexington VAHCS IRB at 859-233-4511 x4927 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

**WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?**
Since this is a one time participation, it is highly unlikely you will be told about any new information.

**WHO COULD PROFIT FROM THE STUDY RESULTS?**
There are no payments other than regular salary to the investigator. There are no real or apparent conflicts to disclose

**DOES THIS STUDY INVOLVE GENETIC RESEARCH? HOW WILL MY GENETIC INFORMATION BE PROTECTED?**
Not applicable

**FUTURE USE OF DATA AND RE-CONTACT**
Not applicable

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

Dr. Babak Bazrgari or a research team member has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure or your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record.

| **I agree to participate in this research study as has been explained in this document.** | | |
|---|---|---|
| _____<br>Participant's Name | _____<br>Participant's Signature | _____<br>Date |
| _____<br>Name of person obtaining consent | _____<br>Signature of person obtaining consent | _____<br>Date |