 Subject ID: _____

Title: Multimodal Imaging Biomarkers for Investigating Fascia, Muscle, and Vasculature in Myofascial Pain

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Multimodal Imaging Biomarkers for Investigating Fascia, Muscle, and Vasculature in Myofascial Pain

INFORMED CONSENT FORM

RESEARCH PROCEDURES

This research is being conducted to develop a clinical outcome measure for myofascial pain syndrome (MPS). We anticipate that this research will lead to improved knowledge of MPS address the need for a diagnostic tool. This research is funded by the National Institutes of Health.

If you agree to participate, you will be asked to participate in a series of up to 3 visits to our lab as well as complete daily and weekly self-reports of pain. The entire duration of your participation will last three months. Each visit is expected to last about 2 hours.

During your first visit, we will perform a comprehensive physical examination to differentiate between participants with MPS and those without. During this physical exam you will be asked to participate in multiple diagnostic tests. These tests include the following: ultrasound of the shoulder area; bioimpedance spectroscopy, which involves sending a small current into tissue at different frequencies and estimating the resistance and reactance; high density electromyography, which measures the electrical activity of muscles; photoacoustic imaging, which is used to measure the oxygenation of muscle tissues; cervical and shoulder range of motion assessment; a windup ratio assessment in which you will be asked to rate your pain in response to a stimulus at your shoulder; a pressure pain threshold assessment also performed at your shoulder; and the NIH HEAL assessment for adult chronic pain.

Following your first visit, you will be asked to return to the lab once a month for three months. During these visits the same diagnostic tests from your first visit will be repeated. You will also be asked to complete a daily self-report of pain, triggered at random points during the day, on a smartphone using the application Metricwire. You will also be asked to allow the application to collect automated activity monitoring from the smartphone sensors. Finally, you will be asked to complete weekly, three-item pain intensity ratings.

RISKS

There are no foreseeable risks for participating in this research. This study will only involve the use of devices that are completely non-invasive. There are no risks associated with the experiments that are greater than everyday living. The risks associated with the proposed electronics are no greater than the risks associated with using standard approved electronics. We will be using the following measurement techniques: ultrasound imaging (shear wave elastography, vibration elastography, doppler, photoacoustic imaging), bioimpedance spectroscopy, high-density electromyography. There are no known risks of using ultrasound imaging, which is routinely used in clinical and research settings. Possible mild discomforts could include the application of a conducting gel to a part of your shoulders. The gel typically dries without flaking and does not have an odor associated with it. We will use an FDA-approved system for bioimpedance spectroscopy that has been widely used for research with human subjects and is of low risk. High density electromyography involves the passive sensing

of electrical activity of muscle by placing an electrode array on the skin surface. There are no known risks of using electromyography. It is widely used for research with human subjects. You will be asked to sit comfortably during all procedures and provided with laser safety goggles when necessary.

In case of injury during testing procedures, the GMU research team may provide basic first aid. If appropriate, the staff will call the emergency response team at 911. Neither GMU nor the investigators have funds available for payment of medical treatment for injuries that you may sustain while participating in this research. Should you need medical care, you or your insurance carrier will be responsible for payment of the expenses required for medical treatment

BENEFITS

There are no benefits to you as a participant other than to further research in the development of quantitative biomarkers for myofascial pain. In the future, results from this study could benefit others who experience chronic myofascial pain.

CONFIDENTIALITY

The data in this study will be confidential. Your name will not be placed on any research data. You will not be identified by name in any report of the results. Data will be kept in a locked filing cabinet. All biomarker data will be stored in a secured and firewalled data server. A code will be placed on the collected data. Only the principal investigator will have access to the identification key. Identifiers may be removed from the data and the de-identified data could be used for future research without additional consent from participants.

There is a possibility that the Food and Drug Administration or the National Institutes of Health may inspect the records. If you choose to withdraw from the study, the researchers cannot remove the data that has already been collected about you.

The Institutional Review Board (IRB) committee that monitors research on human subjects may inspect study records during internal auditing procedures and are required to keep all information confidential.

PARTICIPATION

You may be eligible to participate in this study if you meet the following inclusion criteria:

1. Age 18 or older.

You are not eligible to participate in this study if you meet the following exclusion criteria:

1. Unable to comply with all research procedures
2. diagnosis of fibromyalgia, chronic fatigue syndrome or chronic Lyme disease;
3. Diagnosis of cervical radiculopathy or neuropathy;
4. History of head, neck, cervical spine, or shoulder girdle surgery;
5. Atypical facial neuralgia;
6. New medication or change in medication in past 6 weeks;
7. Current throat or ear infection.

Your participation is completely voluntary, and you may withdraw from the study at any time and for any reason. If you decide not to participate or if you withdraw from the study, there is no penalty or loss of benefits to which you are otherwise entitled. There are no costs to you or any other party. You will receive $50 in cash every time you participate in a study visit.

Under the U.S. federal tax law you may have individual responsibilities for disclosing the dollar value of the incentive received on this study.

CONTACT

This research is being conducted by Dr. Siddhartha Sikdar of the Department of Bioengineering at George Mason University. He may be reached by email at ssikdar@gmu.edu or by phone at 703-993-1539 for questions or to report a research-related problem. You may contact the George Mason University Institutional Review Board office by email at irb@gmu.edu or by phone at 703-993-4121 if you have questions or comments regarding your rights as a participant in the research.

This research has been reviewed according to George Mason University procedures governing your participation in this research.

CONSENT

I have read this form, all of my questions have been answered by the research staff, and I agree to participate in this study.

_____
Signature

_____
Name

_____
Date of Signature