Title: Fibromyalgia TENS in Physical Therapy Study (TIPS): an Embedded Pragmatic Clinical Trial

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INFORMED CONSENT DOCUMENT

Project Title: **Fibromyalgia TENS in Physical Therapy Study (TIPS): an embedded pragmatic clinical trial**

Principal Investigator: Kathleen Sluka, Leslie Crofford, Josiah Sault, (University of Illinois Chicago, 2C Clinic, Chicago, Illinois)

Research Team Contact: Dana Dailey 319-467-4203, Emily Nicklies 312-355-4394

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant.

- If you have any questions about or do not understand something in this form, you should ask the research study team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study called a pragmatic clinical trial – which means that we are focusing on real-world healthcare situations. In this case, the situation is physical therapy treatment. We are inviting you to participate in this research study because you are age 18 or above, have been diagnosed with fibromyalgia, and have been referred to receive physical therapy.

The purpose of this research study is to study a pain treatment called TENS (Transcutaneous Electrical Nerve Stimulation). TENS therapy is used in physical therapy settings to decrease pain. Electrodes attached to the skin on the upper back and low back deliver electrical impulses to nearby nerve pathways. TENS releases chemicals in your body that stop pain signals. The electrodes are controlled by a small unit that is worn on the belt or carried in a pocket. The intensity of the stimulation is set by the user. TENS is frequently used for chronic pain conditions, such as low back pain or knee osteoarthritis. We are conducting this study to determine if adding TENS to routine physical therapy will improve your pain that you have during activity or movement related to your fibromyalgia.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 450 people will take part in this study at 25-35 clinical sites with each site on average enrolling 25 participants (20 to 30 participants per clinic). The study is conducted by investigators at the University of Iowa and Vanderbilt University Medical Center. The University of Iowa serves as both the Clinical Coordinating Center and Data Management Center and will oversee training of each clinical site to perform the trial along with monitoring study data and results.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 26 weeks (approximately 6 months). After you consent to participate in the study, you will continue your prescribed physical therapy in the clinic, and in addition, you will be asked to complete some forms and research homework at home at several timepoints including day 1, day 30, day 60, day 90 and day 180. Some participants will have an additional shortened day of research homework at 65 days.

WHAT WILL HAPPEN DURING THIS STUDY?

You are eligible for this study because you have been told you have fibromyalgia and have been referred to PT with a diagnosis of fibromyalgia , or chronic pain (pain lasting more than three months). You will be assigned to one of two treatment groups: 1) TENS Group - which includes physical therapy and TENS treatment, or 2) No TENS Group - which includes physical therapy alone and No TENS for 2 months, followed by TENS for 4 months

IF YOU ARE ASSIGNED TO THE TENS GROUP (Physical Therapy and TENS for 6 months)

After you complete your consent by electronically signing this document before PT Visit 2, you will be given two TENS units and a quantity of electrodes to use at home or at PT. Your physical therapist will provide instructions on operating the units and how to use the TENS units and electrodes on your upper and lower back. You will be instructed on downloading the Quell Flex App from the App Store (for Apple users) or GooglePlay (for Android users) onto your mobile device. There are no costs or charges associated with downloading or using the Quell Flex App. You will learn how to operate the TENs units manually and also with the Quell Flex App on your device. You will take the TENS home with you for daily use at home, during research homework and each PT session. We want you to wear the TENS at home 2 hours every day, particularly when you are active. Please remember to bring your TENS to each PT session to wear during therapy sessions.

For your research homework, you will be instructed on how to access the electronic data collection website (called "REDCap ™") where you will be asked to rate your pain and fatigue, perform a sit and stand test, put your TENS units on your upper back and low back for 30 minutes while you answer questionnaires about your experience with fibromyalgia, and then perform the sit and stand test again and rate your pain *during* the sit and stand test. If you do not have access to a computer/tablet/phone at home, you may fill out the study forms on paper and FAX or mail them to the study team.

You will be asked to complete home study activities at the following time points after you enroll in the study:

- 1 day
- 30 days
- 60 days
- 90 days
- 180 days

At each time point, you will complete the research homework and enter the results on REDCap™ . We estimate that each of these sessions will take about 45 minutes.

IF YOU ARE ASSIGNED TO THE NO TENS GROUP (Physical Therapy and No TENS for 2 months, then TENS for 4 months)

You will continue physical therapy with your therapist at their treatment location during the prescribed course of physical therapy.

For your research homework, you will be asked to rate your pain and fatigue, perform a sit and stand test, answer questionnaires about your experience with fibromyalgia, and then perform the sit and stand test again and rate your pain and fatigue *during* the sit and stand test. If you do not have a computer/tablet/phone at home, you may fill out the study forms on paper and FAX or mail them to the study team.

You will also be instructed not to use any TENS therapy during the first 60 days.

You will be asked to complete home study activities at the following time points:

- 1 day after enrollment
- 30 days
- 60 days
- 65 days (you will complete this visit with a study staff member, see below)
- 90 days
- 180 days

At each time point, you will complete the research homework and enter your information on REDCap™"). We estimate that each of these sessions will take about 45 minutes.

After completion of the 60-day homework, a study team member will mail you 2 TENS units, written instructions and electrodes. The study team member will set up a time to instruct you how to use the TENS units and electrodes on your upper and lower back and answer any questions you might have. You will be instructed on downloading the Quell Flex App from the App Store (for Apple users) or Google Play (for Android users) onto your mobile device. There are no costs or charges associated with downloading or using the Quell Flex App. You will learn how to operate the TENs unit manually and also with the Quell Flex App on your device. You can also view a presentation about how to use the units. You will begin using TENS daily at home, during research homework and each PT session (if still in PT). We want you to wear the TENS at home 2 hours every day, particularly when you are active. Please remember to bring your TENS to each PT session (if still in PT) to wear during therapy sessions.

You will then complete your day 65 research homework which includes rating your pain and fatigue, performing a sit and stand test, wearing the TENS unit on your upper back and neck for 30 minutes, then perform the sit and stand test again and rate your pain and fatigue during the sit and stand test. You may use the TENS unit on your own after this instruction. We want you to wear the TENS at home 2 hours every day particularly when you are active. You will also complete the home study activities with the TENS unit on at the 90- and 180-day time points.

Data Storage for Future Use

As part of this study, we are obtaining data from you. In the future, after the study is over, we would like to study the data collected from you during your participation in the study. Your data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it will be stripped of identifiers (such as name, date of birth, address, etc.). Other qualified researchers who obtain proper permission may gain access to your data for use in approved research studies that may or may not be related to in the purpose of this study.

The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding fibromyalgia, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products, tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, University of Vanderbilt Medical Center, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of data do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your data will be stored with a code which may be linked to your name, address, date of birth, and medical record number. If you agree now to future use of your data but decide in the future that you would like to have it removed from future research, you should contact Dr. Kathleen Sluka at 319-335-9791. However, if some research with your data has already been completed, the information from that research may still be used.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be stored/shared for future research.

____ Yes ____ No

WILL I BE NOTIFIED IF MY DATA RESULT IN AN UNEXPECTED FINDING?

The results from the data we collect in this research study are not the same as what you would receive as part of your routine health care. The data results will not be reviewed by a physician who normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your data will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your primary care physician.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Likely / Common (more than 35%)

- Local skin irritation caused by the adhesive gel in the TENS electrode pad may occur. The butterfly electrode used for this study has less risk of skin irritation than traditional electrodes. Irritation will be minimized by loosening the electrodes with alcohol or water prior to electrode removal. The skin area will be examined when electrodes are removed and prior to electrode placement. If there is moderate skin irritation, the electrode will be placed in a slightly different area. In an unusual case, if significant disruption of the skin occurs, your study participation may be stopped.

Less Likely / Less Common (10% - 35%)

- Mild redness at the site of TENS stimulation with a burning or prickling sensation usually related to insufficient gel on the pads.

Rare (less than 10%)

- Discomfort from TENS. This usually subsides after the unit has been on for a few minutes. If discomfort persists, adjustments will be made until the discomfort is gone. If the discomfort cannot be relieved, TENS will be discontinued.
- Aggravation of pain or fatigue from TENS.
- There is a rare risk of the loss of confidentiality or loss of personal data with participation in the study.
- There is a rare risk of falling during the sit and stand test at home.

Extremely Rare (less than 1%)

- There is a possibility with the TENS unit model button malfunctioning and increasing the level of intensity on its own. If the TENS unit provided to you in this study increases intensity by itself, shut the unit off and discontinue use of that unit. The study team should be contacted for a replacement unit (see the "What if I Have Questions?" section below for study staff contact information).

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of the knowledge gained about TENS use and fibromyalgia.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether to be in this study, your physical therapist will discuss the other options that are available to you. Instead of being in this study, you could discuss the use of a TENS unit which can be ordered by your physical therapist. The therapy could be performed without participation in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study. You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for each completed study visit via check from the University of Iowa. Compensation is pro-rated per visit as follows:

- First study visit (1 day after enrollment): $40
- 30 day visit: $20
- 60 day visit: $60
- 90 day visit: $20
- 180 day visit: $60

If you do not finish the study, you will be compensated for the visits you have completed. If you complete the study, you will receive a total of $200. You will receive your payment within approximately two weeks after each visit by mail. We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to issue your compensation and for tax reporting purposes to the United States Internal Revenue Service

If you are assigned to the TENS group you will also receive 2 TENS units and a 6 month supply of electrodes. If you are assigned to the No TENS group you will receive 2 TENS units and a 4 month supply of electrodes.

COMPENSATION FOR INJURY

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Sault at 312-355-2626.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. [Include if applicable – The study staff will assist you in obtaining pre-authorization from your insurance company.] Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such

as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

WHO IS FUNDING THIS STUDY?

National Institute of Health National Institute of Arthritis and Musculoskeletal and Skin Disorder (NIH - NIAMS) is funding this research study. This means that the University of Iowa and Vanderbilt University Medical Center are receiving payments from NIH – NIAMS to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH - NIAMS for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

It is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa,
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies), and
- NeuroMetrix (the company that makes the TENS unit).

Loss of your personal data could occur if you mistakenly download a fraudulent Quell Flex App to your personal device in order to operate the TENS unit. To minimize this risk, you will be guided on downloading the correct app during your TENS instruction session with your therapist or a study team member. You are advised not to attempt to download the app without the assistance of your therapist or a study team member to ensure you obtain the correct app.

To help protect your confidentiality, we will collect study data electronically in the REDCap™ platform at the University of Iowa. The TENS unit usage data will be collected through a smart phone platform at NeuroMetrix but will only be identified by study ID. The REDCap™ platform is managed by the Biomedical Informatics group in the Institute for Clinical and Translational Science at the University of Iowa. All data collected for this study will be securely transferred to the University of Iowa College of Public Health. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This Certificate means that the researchers cannot be forced (for example by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. However, a Certificate of Confidentiality does not prohibit the researcher from disclosing information about you or your involvement in this research that you have agreed to disclose or make available. For example, if you request in writing that information about you or your participation in the research be released to an

insurance company, the researcher may not use the Certificate of Confidentiality to withhold this information. This means that you and your family should actively protect your own privacy. Finally, the researcher is not prevented from taking steps, including reporting to appropriate authorities, to prevent serious harm to yourself or others. You may receive a copy of the Certificate of Confidentiality upon request.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Josiah Sault and his/her research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record that is needed for the research and that specifically includes:

- Personal identifiers (your name, address, phone number, date of birth, social security number, medical record number), dates of service, and demographic information (race, gender, ethnicity, age)
- Results of physical examinations
- Medical history
- certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study devices
- Billing information

During the conduct of the research, the researchers may use or share your health information:

- With each other and with other researchers involved with the study.
- With law enforcement or other agencies, when required by law.
- With the sponsor/funding agency of the research, National Institute of Arthritis and Musculoskeletal and Skin Disease and its agents or contractors as required to conduct the research and/or confirm the results of the research.
- With non-UIC collaborators of the research study: The University of Iowa Institutional Review Boards and support staff and the Vanderbilt University Medical Center staff.
- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- United States Government Regulatory Agencies, including but not limited to the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA).

If all information that identifies you is removed from the research data, the remaining information is no

longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

During your participation in this research, you will not have access to the research records or information that is not usually kept in your medical record. However, this information is available to your doctor in the case of an emergency. The researcher may provide you with access to the research records or information related to this research once the study is done.

How will your health information be protected?

The researchers and the National Institute of Arthritis and Musculoskeletal and Skin Disease agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, unless permitted by laws that they have to follow.

Your Authorization for release of health information for this research study does not have an expiration date, but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to: Josiah Sault, 711 W. Maxwell St, Chicago, IL 60607.

If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because in our judgment it would not be safe for you to continue.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Dana Dailey 319-467-4203, Dr. Kathleen Sluka 319-467-4203, Emily Nicklies 312-355-4394. If you experience a research-related injury, please contact: Dr. Dana Dailey 319-467-4203 or Dr. Kathleen Sluka 319-467-4203

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or hipaa@uillinois.edu.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

_____ _____

(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)