CRCNS: Model-based Characterization of Spinal Cord Stimulation for Pain

NCT04732325

June 11, 2023

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Spinal cord stimulation for pain

(Model-based characterization of spinal cord stimulation for pain)

Company or agency sponsoring the study: The National Center for Complementary and Integrative Health (NCCIH)

University of Michigan

Names, degrees, and affiliations of the principal investigator and study coordinator:

Principal Investigator: Scott Lempka, PhD, Departments of Biomedical Engineering and Anesthesiology, University of Michigan

Study Coordinator: Jessica Loechli, B.S., Department of Biomedical Engineering, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is the study of the pain-relieving effects of different types of spinal cord stimulation (SCS). You are receiving SCS as part of your standard of care for chronic pain management. During this study, we will utilize different methods to assess how different types of stimulation help relieve pain.

This research is studying SCS devices already approved by the Food and Drug Administration (FDA) to treat chronic pain. Researchers are studying a large group of people to continue to learn information about how different types of stimulation work to relieve pain. This research will utilize standard surveys and sensory testing. Your health-related information will be collected for this research study.

This study involves a process called randomization. While all participants in this study will receive the same types of stimulation by the end of the study, this means that the order you will receive the different types of stimulation is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in or what type of stimulation you are receiving.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include a loss of confidentiality, physical discomfort during sensory testing and electrical stimulation, claustrophobia, and an exposure to radiation during imaging. It is also possible that during certain types of stimulation some symptoms may worsen, that is the degree of pain relief may vary across different types of stimulation. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by improving our understanding of chronic pain and how to treat it. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 1-2 months. Each visit will take approximately 1-4 hours to perform all of the desired assessments. The screening visit will take approximately 2 hours, the behavioral sessions will take approximately 2 hours, the imaging session will last approximately 1 hour, and each programming session will last approximately 1 hour.

You can decide not to be in this study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Doctors sometimes treat chronic pain with devices that send mild electrical currents into the spinal cord. This type of treatment is referred to as neurostimulation. A common form of neurostimulation therapy is spinal cord stimulation (SCS).

In this study, we want to learn more about how SCS affects pain processing and relieves pain. To find out, we will examine multiple forms of SCS in chronic pain patients who are receiving SCS from their own doctors as part of their standard of care.

This study WILL NOT provide neurostimulation therapy or any other medical treatment. We will examine chronic pain patients who are being treated with SCS by their own doctors as part of their standard clinical care.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. **Whether or not you participate in this study will have no effect on your standard clinical care for chronic pain management.**

3.1 Who can take part in this study?

You may be able to take part in this study if:

- You are at least 18 years old
- You can speak, read, and understand English
- You suffer from chronic pain
- You are undergoing spinal cord stimulation (SCS) as part of your standard of care for chronic pain management
- You understand study procedures and can comply with them for the entire length of the study
- You are willing to participate in COVID-19 symptom screening and answer questions about COVID-19 diagnosis before a scheduled visit.
- You are willing to wear a face covering during study visits.

You CANNOT take part in the study if:

- You are pregnant or nursing
- You have artificial nails, nail enhancement, or nail extensions (within the past year that cover any part of either thumbnail)
- You are unable or unwilling to undergo any of the study tests
- You have any other conditions or circumstances that we believe would interfere with your participation
- You currently have or tested positive in the last 14 days for COVID-19, or are symptomatic for COVID-19

3.2 How many people are expected to take part in this study?

We expect to enroll 25 patients in this study who are receiving SCS as part of their clinical care for chronic pain management.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

For some research studies, such as the one you are being asked to join, it is important that you do not learn the results of certain tests. Whether you intend it or not, sometimes learning this information may make you change your actions and behaviors in ways that could impact the outcome of the study. As described in Section 1, this study involves a process called randomization. While all participants in this study will receive the same types of stimulation by the end of the study, this means that the order you will receive the different types of stimulation in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in or what type of stimulation you are receiving.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments and report any adverse reactions you may have during the study.

If you meet eligibility criteria, you will be asked if you would like to enroll in the study. If you enroll, we will invite you to be part of the following study visits. **Participation involves up to six visits**. Visits 2-6 include two main session types: 1) **behavioral session** that involves assessment of your pain using several questionnaires and sensory testing procedures, and/or 2) **programming session** that involves adjusting the settings on your SCS stimulator. Visit 2 will also include an **imaging session** in which you undergo a computed tomography (CT) scan.

Visit 1: Screening and Enrollment Visit

You will visit our clinic at the Michigan Clinical Research Unit (MCRU) facility, in Lobby M of the Domino's Farms complex in Ann Arbor or at our Back and Pain Center clinic at the Burlington building in Ann Arbor. At this visit, we will find out if this study is right for you and, if so, enroll you in the study. We will ask you about your medical, social, and psychiatric history and perform various clinical assessments. We will ask you to complete a set of questionnaires about your treatment history, medications, symptoms of chronic pain, and impact of chronic pain on your daily life. We will collect your vital signs (heart rate, blood pressure, respiration rate, and body temperature), height, and weight. We will also show you the devices to be used in this study. This will give you an opportunity to practice the tests, familiarize yourself with the study devices and answer any questions you may have about them.

Finally, if you are a woman and able to become pregnant, we will also ask you to provide us with a urine sample so that we can make sure you are not pregnant. If you are pregnant, you cannot take part in the study.

If we find that you don't qualify for the study, your participation will be over. If you do qualify and you are interested in participating in the study, we will schedule your next visits.

Visit 2: First treatment visit

Behavioral session: You will come back to our clinic at Domino's Farms or to our Back and Pain Center clinic at the Burlington building for a behavioral session. This session may also occur on the same day as the screening and enrollment visit. During this session, we will collect your vital signs (heart rate, blood pressure, respiration rate, and body temperature), height, and weight. We will ask you to rate your current pain on a scale. We will ask you to complete several (at least 11) questionnaires about your symptoms of chronic pain. We will measure your pain sensitivity to different stimuli, such as pressure-pain and vibration. We will also do other tests to examine how your body naturally controls pain. A short summary of each of these tests is provided at the end of section 4.1.

Programming session*:* During this session, we will adjust the settings on your SCS stimulator to obtain various clinical measurements. These measurements will include the point at which you will first feel the stimulation (usually as a tingling sensation) and the point at which the stimulation starts to feel uncomfortable. We will also ask you to indicate where you feel a tingling sensation by drawing on a human figure or on a tablet. We will test additional stimulation settings on your SCS device. We will ask you to rate your pain on a scale, indicate how much of your painful areas the stimulation reaches, and complete some questionnaires.

Near the end of this programming session, we will adjust the settings on your SCS device. When performing these adjustments, you may or may not feel the stimulation (usually as a tingling sensation). After the adjustments are complete, you will not be able to change the stimulation settings for the next week.

Imaging session**:** You will go to the University of Michigan (UM) Hospital for an imaging session. This session may occur on the same day as the behavioral session or occur on a different day. During this session, we will use a computed tomography (CT) machine to obtain images of your spine. A CT machine uses X-rays to create images of the inside of your body. CT does expose you to some radiation (see section 5, below, for CT risks). The CT scans will show us the location of your SCS implant. If you are a woman and able to become pregnant, we will ask you to provide us with a urine sample prior to the CT scan so that we can confirm that you are not pregnant.

Visit 3: Second treatment visit

Approximately 1 week after Visit 2, we will ask you to come back to our clinic at Domino's Farms or to our Back and Pain Center clinic at the Burlington building for Visit 3. At this visit, you will have another *behavioral session* and *programming session,* during which we perform the same procedures as those performed in the previous visit.

Near the end of this programming session, we will again adjust the settings on your SCS device. When performing these adjustments, you may or may not feel the stimulation (usually as a tingling sensation). After the adjustments are complete, you will not be able to change the stimulation settings for the next week.

Visit 4: Third treatment visit

Approximately 1 week after Visit 3, we will ask you to come back to our clinic at Domino's Farms or to our Back and Pain Center clinic at the Burlington building for Visit 4. At this visit, you will have another

behavioral session and *programming session,* during which we perform the same procedures as those performed in the previous visit.

Near the end of this programming session, we will again adjust the settings on your SCS device. When performing these adjustments, you may or may not feel the stimulation (usually as a tingling sensation). After the adjustments are complete, you will not be able to change the stimulation settings for the next week.

Visit 5: Fourth treatment visit

Approximately 1 week after Visit 4, we will ask you to come back to our clinic at Domino's Farms or to our Back and Pain Center clinic at the Burlington building for Visit 5. At this visit, you will have another *behavioral session* and *programming session,* during which we perform the same procedures as those performed in the previous visit.

Near the end of this programming session, we will again adjust the settings on your SCS device. When performing these adjustments, you may or may not feel the stimulation (usually as a tingling sensation). After the adjustments are complete, you will not be able to change the stimulation settings for the next week.

Visit 6: Final study visit

Approximately 1 week after Visit 5, we will ask you to come back for your last *behavioral session* and *programming session*. These sessions will consist of the same procedures as those performed at the previous visits. At the conclusion of this visit, research staff will debrief the study with you and your SCS device will be returned to its original settings.

The chart below outlines the six study visits.

ORDER OF STUDY VISITS	WHEN WILL IT HAPPEN?	STUDY PROCEDURES THAT WILL BE PERFORMED
Visit 1: Screening & Enrollment visit		• Eligibility review, informed consent • Psychological screening, medical history • Pain assessment (using questionnaires) • Familiarization of sensory testing procedures
Visit 2: First treatment visit	Same day as the screening/enrollment visit OR within 2 months of the screening/enrollment visit	• Behavioral session • Programming session • Imaging session (CT)
Visit 3: Second treatment visit	1 weeks after Visit 2	• Behavioral session • Programming session

Visit 4: Third treatment visit	1 weeks after Visit 3	• Behavioral session • Programming session
Visit 5: Fourth treatment visit	1 weeks after Visit 4	• Behavioral session • Programming session
Visit 6: Final study visit	1 weeks after Visit 5	• Behavioral session • Programming session • Debrief

Sensory testing procedures

Multimodal Automated Sensory Testing (MAST): We will use MAST to assess your sensitivity to pressure-pain. We will deliver mechanical stimuli (using the MAST device) in the form of automatic ascending pressures onto your thumbnail bed.

Vibrometry: We will use vibrometry to assess your sensitivity to non-painful vibration. We will deliver vibratory, non-painful stimuli (using a handheld vibrometer) to your primary pain site and several other control sites (e.g., hand, shoulder).

Algometry: We will use algometry to assess your sensitivity to pressure-pain. We will deliver pressure-pain stimuli (using a handheld analog pressure algometer) to your primary pain site and several other control sites (e.g., hand, shoulder).

Pointed skin probe testing: We will use a handheld, pointed skin probe to deliver a fixed intensity stimulus to your primary pain site and several other control sites (e.g., hand, shoulder) to assess your sensitivity to pricking pain.

Conditioned Pain Modulation (CPM) testing: We will use the CPM test to examine how your body naturally controls pain. We will deliver pressure (using the algometer) to your primary pain site and control sites, before and after application of a contralateral thumbnail pressure (using MAST).

Besides the information about the main study, the following information is specific to unspecified future use of study data. We would also like your permission to keep some of your study data and medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your study data and medical information for future research.

If you give us your permission, we will use your study data and medical information for future research. Even if you give us permission now to keep some of your study data and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your study data we may not be able to take the information out of our research.

We may share your study data and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have

shared your study data and medical information with other researchers, we will not be able to get it back.

The only possible risk the future research may pose is a loss of privacy. Upon the completion of this study, all patient-identifying information will be deleted and there will not be a way to connect your study data with you. Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your study data. Allowing us to do future research on your study data and medical information will not benefit you directly.

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies. Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

4.2 How much of my time will be needed to take part in this study?

Your total time commitment is approximately 20 hours over the next 1-2 months. You will participate in up six research visits, and each visit is expected to last about 1-4 hours.

4.3 When will my participation in the study be over?

Your participation in the study will be over at the conclusion of Visit 6 (about 1-3 months from now).

4.4 What will happen with my information and/or biospecimens used in this study?

With appropriate permissions, your biospecimens and your collected information may be used for future research. The future research may be similar to this study or may be completely different.

With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Risk of outcome measures:
The outcome measurements during this study, including pain ratings and questions on the personal symptom surveys, may cause some discomfort or personal distress. You may refuse to answer any question on the questionnaires or surveys that may be uncomfortable.

Risks related to electrical stimulation:
During the stimulator programming session, electrical currents sent to your spinal cord are titrated over a range of amplitudes. Side effects related to higher currents, such as muscle contractions may occur, but are known to be reversible by either reducing the amplitude of stimulation or stopping the stimulation entirely. Whenever using electricity to stimulate tissue, there is also the possibility of a shock hazard, including an electrical burn. However, only electrical stimulators approved by the United States Food and Drug Administration for spinal cord stimulation (SCS) will be used in this study. Therefore, the risk of tissue damage or electrical shock during the electrical stimulation is minimal.

Risk related to sensory testing:
Overall, your comfort and well-being are very important to us and we have designed the sensory testing experiments following strict safety standards and to be as brief as possible. We limit the intensity of each stimulus to levels that are deemed safe and acceptable. Furthermore, study personnel are trained to be sensitive to your discomfort and concerns. You can inform the person to stop the sensory testing at any time that the pain or unpleasantness of the task becomes uncomfortable. Some of the sensory testing experiments (e.g., pressure-pain testing, non-painful vibratory testing, pointed skin probe testing) in this study may cause some temporary physical discomfort at the body areas that are tested. However, these symptoms may cause indentation and skin reddening resolved in two hours. We will halt these tests automatically if you report severe pain, or at any time if the testing becomes too uncomfortable.

The Multimodal Automated Sensory Testing (MAST) may cause some temporary physical discomfort and temporary redness on the thumbnail. The MAST system includes multiple software, electrical, and mechanical safeguards to ensure that the amount of pressure applied does not exceed safe limits, including a safety release pin that you can pull to immediately release the pressure actuator from your thumb. The test is terminated at or before 10 kg/cm^2 of pressure which is a commonly used maximum pressure level in human sensory testing and does not result in physical injury. You can also stop the stimulus at any time or express instructions to stop the stimuli. You can also withdraw your thumb from the device.

Risks related to X-ray computed tomography (CT):
If you are a chronic pain patient and participate in this study, you will have a CT scan taken after your SCS device is implanted that is not part of your usual medical treatment. CT scan technology uses radiation. Excess radiation exposure can increase the risk of cancer. The amount of added radiation for this study is like being exposed to as much as 2 to 4 years' worth of everyday exposure from the sun and other environmental radiation (3 mSv per year). The risk of cancer due to this added exposure is very small compared to the natural risk of cancer.

Risk of loss of confidentiality:
Additionally, there may be a risk of loss to confidentiality or privacy. The researchers involved in this study will have initial access to your name and/or other identifiable information. This is the case for any standard of care treatment. But, we will take several measures to minimize the risk of possible loss of confidentiality. For example, we will assign you a subject number to use in place of your name for research analyses and we will electronically and physically secure your identifiable data/information. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

Additional imaging procedures (CT) performed as part of this study are for research purposes only. They are not meant to diagnose illnesses, find tumors, or detect any other defects. However, there is still a chance that this imaging could show a defect that is already in your body, such as a cyst or tumor. Many such defects are not important, but you may want to look into them further. Such a finding might require more studies, and maybe even medical treatment, neither of which would be paid for by the investigators, the sponsor, or the University of Michigan.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Your participation in this study is entirely **voluntary**. The alternative option is not to participate in the study. Your clinical care will not be affected by your decision to participate or to not participate in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information."

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There is no harm to you if you decide to leave the study early.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in Section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you will have to arrange for treatment on your own, as the study will not provide medical treatment or provide any compensation to you. You or your insurance provider will be billed for all costs of treatment for sickness or injury caused by the study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will be paid up to $700 for participating in this study and will be compensated as follows for each of the visits:

- $20 for completing the screening visit
- $40 for completing each behavioral session (total for up to six possible sessions = $240)
- $100 for completing the imaging session (total for up to one possible session = $100)
- $20 for each programming session (total for up to five possible sessions = $100)
- $40 for questionnaires (total for up to 6 possible sessions = $240)

You may also qualify for lodging (if you live more than 1.5 hours away) or transportation as needed.

8.3 Who could profit or financially benefit from the study results?

Dr. Clauw and Dr. Harte (who are both on the study team), along with the University of Michigan, have an interest in one of the pain-testing devices (MAST device) used in this study. In the future, they might receive a part of the profits from any sales of the device. Additionally, Dr. Lempka (principal investigator) and the University of Michigan have an interest in the technology used in this study. This technology is licensed to a company called Hologram Consultants, which is partly owned by Dr. Lempka. Should this study prove successful, the University, the company, and Dr. Lempka may benefit financially.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Every effort will be made to maintain your privacy. You will be given a unique study identification number. This number will be used to record your study information. You will never be tracked through the study by name, medical record number, or other personal identifier. A log of participants' names, ID numbers, and personal information (such as home address, telephone number, and emergency contact information) will be maintained in a study file and/or on a computer in a locked area at the clinical site and/or at our research offices. Only authorized members of the research study will have permission to see these data.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. All data will be retained in your study file for approximately 7 years. Then the data will be destroyed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	**Scott F. Lempka, PhD**
Mailing Address:	2800 Plymouth Road, NCRC 014-184 Ann Arbor, MI 48109-2800
Telephone:	(734) 764-2401
Study Coordinator:	**Jessica Loechli, B.S.**
Mailing Address:	2800 Plymouth Road, NCRC 010-A163S Ann Arbor, MI 48109
Telephone:	(734) 647-9052

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the signed and dated copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Contact for Future Studies

We would like to ask your permission to re-contact you about future studies on chronic pain conditions. Participation in any future studies, as with the current study, is entirely voluntary. Please respond to the following statement and CHECK either "YES" or "NO" and write your initials and todays date:

_____ Yes, I agree to be contacted for future research studies

_____ No, I do not agree to be contacted for future studies

Initials: _____

Date: _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____