********************DO NOT DELETE OR ALTER THIS PAGE********************

CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION. Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.

****

INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**:** **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

DO NOT delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

DO NOT upload a clean version of the consent**.**

---------- IRB OFFICE USE ONLY ----------

Study ID: HUM00066475 / Continuing Review ID: CR00078775

Approval Date: 10/14/2019

Document Finalized: 10/15/2019 3:44 PM

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

Neuroimaging Approaches to Deconstructing Acupuncture for Chronic Pain

1.2 Company or agency sponsoring the study:

National Institutes of Health/National Center for Complimentary & Alternative Medicine (NIH/NCCAM)

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Richard Harris, PhD – Department of Anesthesiology, University of Michigan

Daniel Clauw, MD – Department of Anesthesiology, University of Michigan

Steven Harte, PhD – Department of Anesthesiology, University of Michigan

Alex Tsodikov, PhD – School of Public Health, University of Michigan

Daniel Harper, PhD – Department of Anesthesiology, University of Michigan

Suzanna M. Zick, ND, MPH, University of Michigan Integrative Medicine

Vitaly Napadow, PhD – Massachusetts General Hospital

Richard Edden, M.Sc., PhD – Johns Hopkins Medicine

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of the study is to evaluate the effect of acupuncture on pain symptoms in fibromyalgia patients and, to investigate the underlying mechanisms behind the effects of acupuncture. This will be achieved by performing imaging of the brain and comparing scanning results of fibromyalgia patients who have undergone 2 different types of acupuncture treatments to those of control participants without fibromyalgia.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

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.

3.1 Who can take part in this study?

Fibromyalgia Subjects

- Females age 18-65 with symptoms of fibromyalgia for at least 1 year.
- Right handed
- Willing to limit the introduction of any new medications or treatment modalities for control of fibromyalgia symptoms during the study.
- Able to travel to the study site to receive acupuncture treatments up to two times weekly.

Control Subjects

- A control subject can be considered a healthy individual, who is being studied to see how their symptoms or behaviors compare to a group of individuals who suffer from a certain health disorder, such as fibromyalgia.
- Females aged 18-65, who do *not* have fibromyalgia or an associated pain disorder, including: migraine, temporomandibular joint disorder (TMJ), chronic pelvic pain (CPP), or chronic fatigue syndrome (CFS).
- Right handed

You may NOT take part in this study if:

- You have had acupuncture within the last 6-months.
- You have a blood clotting abnormality or bleed easily which may preclude the safe use of acupuncture.
- You have an autoimmune or inflammatory disease that causes pain, such as rheumatoid arthritis, systemic lupus erythematosus, inflammatory bowel disease, etc., or any other chronic pain condition with pain greater than FM pain.
- Peripheral neuropathy of known cause that interferes with activities of daily living.
- History of vascular surgery in lower limbs or current lower limb vascular dysfunction.
- History of head injury with substantial loss of consciousness.
- You routinely (daily) use of narcotic analgesics, marijuana or have a history of substance abuse.
- You use stimulant medications, such as those used to treat ADD/ADHD or fatigue (e.g., amphetamine/ dextroamphetamine [Adderall®], methylphenidate, dextroamphetamine, modafinil).
- You are currently participating in other therapeutic trials, or completed the trial within the last 30 days.
- You are pregnant or nursing.
- You have a severe psychiatric illness.
- Active substance abuse disorder in the past 24 months as determined by subject self-report.
- You have any contraindications to MRI methods. These may include but are not limited to: surgical clips, surgical staples, metal implants, and certain metallic dental material.
- Use of over the counter pain medications (NSAIDs, etc.) on day of MRI scan.
- Use of as needed narcotic pain medication 48 hours prior to MRI scan.
- Current, habitual, or previous use within the last 12 months of artificial nails, nail enhancements, or nail extensions that cover any portion of either thumbnail. Exceptions, including brief and/or occasional use, may be permissible at the discretion of the principal investigator.

- You have any impairment, activity or situation that in the judgment of the Study Coordinator or Principal Investigator would prevent satisfactory completion of the study protocol.
- Contraindications to the Electrostimulator device: Participants with electrical implants (i.e. pacemakers, defibrillators), cardiac rhythmic disorders, seizure disorders, any skin disorders in the vicinity of the electrode or any malignant diseases in the region of application. *(Fibromyalgia participants only)*
- Subjects with Worker's Compensation, Workman's Compensation, civil litigation or disability pertinent to the subject's fibromyalgia; current involvement in out-of-court settlements for claims pertinent to the subject's fibromyalgia; or currently receiving monetary compensation as a result of any of the above.

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

A total of 120 people are expected to take part in the study: 80 people with fibromyalgia and 40 otherwise pain-free volunteers, or "controls".

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Fibromyalgia Patients

Screening and Study Enrollment

If you agree to take part in this research, you will be invited to participate in a screening and instructional session, which will take place at the MCRU facility, located Lobby M of the Domino Farms office complex in Ann Arbor. This visit will last about 90 minutes and will involve an interview with the study coordinator about your medical, social and psychiatric history. We will confirm you meet the fibromyalgia criteria and perform a fibromyalgia tender point exam. This involves the examiner applying pressure to different points on your neck, back, hips, arms and legs and you reporting when it is painful. Finally we will demonstrate devices used in this study, including the calf cuff and MAST devices that will be used throughout the study to measure your pain. This will give you an opportunity to practice the tests, familiarize yourself with the study devices and ask any questions you may have about them.

We will also ask you to give us a urine sample if you are of child bearing potential so we can make sure you are not pregnant. Finally, we will ask you to complete several short questionnaires about yourself and your symptoms.

Once deemed eligible by the study coordinator and investigator we will schedule your research visits.

Baseline Behavioral Session

The Behavioral Session will occur at the MCRU facility, located in Lobby M of Domino Farms within 30 days of your screening visit and may occur on the same day as the screening visit. At this visit you will complete several paper surveys about your pain, functioning and fibromyalgia symptoms. We will then begin the pain assessments.

The pain assessments involve using two automated devices to apply pressure to your thumb and to your calf. For thumb pain a special computer, operated by a trained research technician, will lower a rubber stopper onto your thumbnail and will apply a 5-second range of pressure (from less pressure to more pressure). For your calf pain a pressure cuff will be wrapped around your lower leg.

First, we will determine the range of pressure you find tolerable. We'll start with a low intensity of pressure and then increase it, according to your rating of pain intensity. For each of the pressure assessments, you will be asked to rate the intensity (e.g., mild, moderate, or intense) and the unpleasantness (e.g., annoying, unpleasant) of these sensations on a scale, and be asked to rate the pressures on a numerical or analog pain visual scale.

We will then do some more tests using the pain assessment device, this time a random method (i.e., by chance) will decide how much pressure to put on your thumbnail. The amounts of pressure will be the same as in the first set of tests, but in a random order.

For the cuff pain assessment, we will have you remain in a seated position in a chair with your foot resting on a support at a slightly elevated position. We will attach an inflatable cuff (similar to a blood pressure cuff) to you lower leg just below the knee. We will then inflate the cuff to determine the range of pressure pain you find tolerable –just as we did with your thumb.

For the visual stimulation assessment, we will ask you to look at a flashing checkerboard image on a computer screen or by wearing special glasses. The flashing speed, color, shape and brightness of this image may change several times while viewing it. You will be asked to rate its intensity and unpleasantness every time it changes. This assessment may occur both outside and inside of the MRI.

We'll take a short break and do this test again; this time we will apply pressure to both your thumb and lower leg.

The pain assessments will last about 1 hour in total (with breaks). The entire research visit is expected to last 2 hours.

You will be provided with the Food Frequency Questionnaire, along with a self-addressed stamped envelope to complete at home and mail back the following week. This will take you approximately 20 minutes to complete.

Baseline MRI Scan

1 to 3 days after your baseline Behavioral visit you will meet the research team at the MRI scanner located at the University of Michigan Hospital.

We will use functional Magnetic Resonance Imaging (fMRI) to monitor areas of the brain that are involved in thinking and processing pain. The scanner stimulates the brain to send out signals that we will record and analyze.

The fMRI procedure involves lying on a table that slides into a hollow machine. You will lie in the scanner with a coil around your head. This coil keeps your head still so the magnet can obtain clear images of your head and the blood flow in your brain. During the scan, we will take images of your brain function, some while you are resting and others while we are assessing your pain - using the same assessments we did during the behavioral session.

For each fMRI scan, you will spend about 120 minutes in the scanner.

Prior to undergoing the MRI scan, if you are of child-bearing potential, you will be required to complete a urine pregnancy test to confirm that you are not pregnant. We will also have you complete an MRI Safety Screen to ensure it is safe for you to undergo an MRI.

The entire research visit is expected to last 3 hours.

Treatment

Twice a week for 4 weeks, you will come to the MCRU facility, located in Lobby M of Domino Farms to receive acupuncture. At the start of the first treatment you will be randomly assigned – like drawing straws – to receive either electro-acupuncture or laser acupuncture:

- During electro-acupuncture, 9 acupuncture needles will be inserted at specific locations of your body. A low electrical current is run through the needles for about 25 minutes.
- Laser acupuncture involves an intense light being shone over the same locations used in electro-acupuncture. However, unlike electro-acupuncture there will be no physical contact between device and your skin. The laser acupuncture will also take 25 minutes to complete.

The treatment will be performed by a licensed acupuncturist trained in both acupuncture methods being studies. For your safety, you will wear a blindfold throughout the procedure. At the beginning and end of each session we will ask how you are feeling and once a week we will have you complete a survey about your fibromyalgia symptoms.

Each acupuncture research visit is expected to last 30 minutes.

Follow-Up Behavioral Session and Scan

The Follow-Up Behavioral Session and Scan will follow the same format as the baseline sessions. They will be scheduled to take place the week after your final acupuncture treatment.

Control Participants

Screening and Enrollment

If you agree to take part in this research, you will be invited to participate in a screening and instructional session, which will take place at the MCRU facility, located Lobby M of the Domino Farms office complex in Ann Arbor. This visit will last about 90 minutes and will involve an interview with the study coordinator about your medical, social and psychiatric history. We will confirm that you do not have fibromyalgia and perform a tender point exam. This involves the examiner applying pressure to different points on your neck, back, hips, arms and legs and you reporting when it is painful. Finally we will demonstrate pain testing devices used in this study, including the calf cuff and MAST devices that will be used throughout the study to measure your pain. This will give you an opportunity to practice the tests, familiarize yourself with the devices and ask any questions you may have about them.

We will also ask you to give us a urine sample if you are of childbearing potiential so we can make sure you are not pregnant – a requirement for undergoing an MRI. Finally, we will ask you to complete several short questionnaires about yourself. Once deemed eligible by the study coordinator and investigator we will schedule your behavioral session and MRI scan.

Behavioral Session

The behavioral session will occur at the MCRU facility, located Lobby M of the Domino Farms within 1 month of your screening visit and may occur on the same day as the screening visit. At this visit you will complete several paper surveys about your pain, functioning and other symptoms. We will then begin the pain assessments.

The pain assessments involve using two automated devices to apply pressure to your thumb and your calf. For the thumb pain a special computer, operated by a trained research technician, will lower a rubber stopper onto your thumbnail and will apply a 5-second range of pressure (from less pressure to more pressure). For your calf pain a pressure cuff will be wrapped around your lower leg.

First, we will determine the range of pressure you find tolerable. We'll start with a low intensity of pressure and then increase it, according to your rating of pain intensity. For each of the pressure assessments, you will be asked to rate the intensity (e.g., mild, moderate, or intense) and the unpleasantness (e.g., annoying, unpleasant) of these sensations on a scale, and be asked to rate the pressures on a numerical or analog pain visual scale.

For the cuff pain assessment, we will have you remain in a seated position in a chair with your foot resting on a support at a slightly elevated position. We will attach an inflatable cuff (similar to a blood pressure cuff) to you lower leg just below the knee. We will then inflate the cuff to determine the range of pressure pain you find tolerable –just as we did with your thumb.

For the visual stimulation assessment, we will ask you to look at a flashing checkerboard image on a computer screen or by wearing special glasses. The flashing speed, color, shape and brightness of this image may change several times while viewing it. You will be asked to rate its intensity and unpleasantness every time it changes. This assessment may occur both outside and inside of the MRI.

We'll take a short break and do this test again; this time we will apply pressure to both your thumb and lower leg.

The pain assessments will last about 1 hour in total (with breaks). The entire visit is expected to last 2 hours.

You will be provided with the Food Frequency Questionnaire, along with a self-addressed stamped envelope to complete at home and mail back the following week. This will take you approximately 20 minutes to complete.

MRI Scan

1 to 3 days after your Baseline Behavioral visit you will meet the research team at the MRI scanner located at the University of Michigan Hospital.

We will use functional Magnetic Resonance Imaging (fMRI) to monitor areas of the brain that are involved in thinking and processing pain. The scanner stimulates the brain to send out signals that we will record and analyze.

The fMRI procedure involves lying on a table that slides into a hollow machine. You will lie in the scanner with a coil around your head. This coil keeps your head still so the magnet can obtain clear images of your head and the blood flow in your brain. During the scan, we will take images of your brain function, some while you are resting and others while we're assessing your pain using the same assessments we did during the behavioral session.

For each fMRI scan, you will spend about 120 minutes in the scanner.

Prior to undergoing the MRI scan, we will offer a urine pregnancy test to confirm that you are not pregnant. We will also have you complete an MRI Safety Screen to ensure it is safe for you to undergo an MRI. As a control your participation in the study will be complete at the conclusion of this visit.

Imaging Repository

This study is part of the Pain and Interoception Imaging Network (PAIN), an imaging repository at University of California Los Angeles (UCLA). The PAIN initiative is supported in part by NIH and by the Gerald Oppenheimer Foundation. The PAIN repository is specifically targeted towards using neuroimaging for discovery of mechanisms and biomarkers related to chronic pain and chronic pain treatment.

This part of the study is optional and you may decline to participate in the repository. By agreeing to participate in the optional repository, you are authorizing us to release coded data from your MRI scans to the PAIN repository. Data donated will not include any information that might directly identify you. The repository data/images will be stored indefinitely and can be accessed by other PAIN investigators. You will be asked to agree or disagree to this portion of the study at the end of this consent form.

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

Fibromyalgia Patients

The total time commitment for FM patients is about 10 weeks. This includes a 4 week window for the screening and 1 week for the baseline sessions and scan; 4 weeks of acupuncture and; 1 week for the follow-up evaluation and scan. The Screening and Behavioral visits can be completed on the same day where appropriate.

- The Screening visit will last 90 minutes.
- The baseline Behavioral session will last 2 hours.
- The Food Frequency Questionnaire completed at home will take 20 minutes.
- The baseline Imaging (MRI) visit will last 3 hours.
- The 8 Treatment sessions will last 30 minutes each.
- The follow-up Behavioral session will last 2 hours.
- The follow-up Imaging (MRI) visit will last 3 hours

Control Patients

The total time commitment for control subjects includes a 4 week window for screening, and one week for the evaluation and scan. The Screening and Behavioral visits can be completed on the same day where appropriate.

- The Screening visit will last 90 minutes.
- The Behavioral session will last 2 hours.
- The Food Frequency Questionnaire completed at home will take 20 minutes.
- The Imaging (MRI) visit will last 3 hours.

4.3 When will my participation in the study be over?

You participation in the study is over at the conclusion of the follow-up imaging (MRI) visit. Control participants study participation is over after their only imaging (MRI) visit.

The entire study will last about 5 years.

4.4 What will happen with my information used in this study?

Your collected information may be shared with U.S. Department of Health and Human Services - National Institutes of Health

Your collected information may also be shared with other researchers, both here or around the world, or with companies. Any sharing is subject to contractual obligations with the Sponsor.

Additionally: With appropriate permissions, your identifiable collected information may be shared, without your additional consent, your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies.

5. INFORMATION ABOUT 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:

- *Self-report Questionnaires:* There is a possibility of discomfort associated with being asked personal questions about health history, symptoms, or emotional feelings.
- *Food Frequency Questionnaire:* This questionnaire asks you about the frequency of various things in your diet. It is expected to take approximately 20 minutes for you to complete. You will be provided with a paper copy of this questionnaire to take home to complete. You will be provided with a self-addressed stamped envelope to return the questionnaire to us the following week. The questionnaire, which will not contain any identifying information about you, will be shipped to Laura Sampson, a researcher at the Harvard School of Public Health, for analysis.
- *Tenderpoint and Quantitative Sensitivity Testing*: The tender point exam may cause discomfort at the testing sites and the pressure sensitivity exam may result in discomfort or bruising at the thumb. There is a possibility of temporary discomfort to the thumb.
- *Calf Cuff*: Risks of cuff pain include mild transient bruising associated with inflation of the cuff which is estimated to occur is less than 5% of cases.
- *Visual Stimulation Assessment:* The possible discomfort of the visual stimulation task may be headache or nausea while or after performing this task.
- *Acupuncture Treatments*: The most common complications associated with acupuncture are generally mild and include: fainting, localized skin infection, increased pain, and nausea and vomiting. More serious problems such as serious skin infections are rare.
- *fMRI and ^{1}H-MRS:* There may be some slight discomfort from noise produced by the MRI machine; individuals will be provided with foam earplugs or headphones. The primary risks known to occur from MRI are due to the magnet's ability to pull metal objects toward it. This pull can cause metal objects in the body (e.g. surgical clips or staples) to move and cause bleeding or disruption of surrounding tissue. Metal objects carried or worn by a person (e.g. jewelry, hair clips, tools) can be pulled toward the magnet and, if free to fly through the air,

could strike an individual. The MRI can cause pacemakers or stimulators implanted in the body to malfunction. There is also a risk that metallic objects in or on the body may be heated by the radio frequency waves, possibly causing burns. Individuals will be screened for implanted metal objects and will be asked to remove all other metal objects. Also, claustrophobia may be problematic, and individuals will be screened for this problem. Women of childbearing potential will be screened for pregnancy with a urine pregnancy test immediately before they enter the scanner. Finally, there exists a potential to cause peripheral nerve stimulation (PNS). PNS is a light touching sensation on the skin surface, lasting only a few seconds. It may cause mild discomfort, but it is not harmful.

The researchers will try to minimize these risks by:

- *Self-report Questionnaires:* You may refuse to answer any question on the questionnaires or surveys that may be uncomfortable.
- *Food Frequency Questionnaire*: There is no known risk of responding to this questionnaire. You are free to skip over any question you do not wish to answer.
- *Tender Point and Quantitative Sensitivity Testing:* Researchers will be educated in how to perform these tests safely. You may stop either test at any time if the testing becomes too uncomfortable.
- *Calf Cuff:* Researchers will be educated in how to perform these tests safely. You may stop the tests at any time if the testing becomes too uncomfortable. A simple button press can rapidly deflate the cuff, ensuring subject safety. You will be able to notify us of any distress and terminate the scan at any time.
- *Visual Stimulation Assessment:* If you find any discomfort while wearing the video eyewear or looking at the flashing checker board or fixed plus sign, you may stop the test at any time. Participants with a history of migraines will not participate in the visual portion of the study.
- *Acupuncture Treatments:* All risks will be minimized by using proper technique: the skin will be cleaned thoroughly before needles are applied; needles to be used are sterile and will be disposed of after each use. The electrical stimulation device can be turned off immediately if the participant experiences pain. A licensed acupuncturist will perform all procedures. Follow-up evaluation by the acupuncturist will include inspection of the skin at needle sites immediately following removal to monitor for any complications.
- *MRI Scan:*
    - To ensure safety for the MRI procedure all participants will be asked to bring or wear clothing without metal fasteners, and remove jewelry and any other metal objects from their body. We will also assess whether metallic objects that may be implanted (e.g., surgical clips or staples) are hazardous or acceptable.
    - We will provide pads and blankets to make sure you are as comfortable as possible while lying in the scanner. Additionally, you will wear foam earplugs to reduce the loud noises made by the scanner.
    - If you experience any sort of discomfort during the MRI procedure at any time, the researchers can stop the scan. You will be able to talk to the MR technician throughout the protocol, and will be able to let them know immediately if you want to stop the procedure and exit the scanner. All participants will be able to end the pain testing session at any time by saying 'Stop'. The investigators will be sitting in the control room and in the MRI-suite, present at all times.
    - The MRI machine is operated within FDA guidelines so the potential for inducing PNS is low.
    - If a female participant is of childbearing potential, they will be required to use an appropriate and effective method of birth control during their participation in this study given the unknown risk of the magnet to the fetus. We will inform participants that these methods can be discussed with their physician. Women of childbearing potential will be asked to take a urine pregnancy test the day of fMRI testing. If you do not wish to take the pregnancy test, you may be excluded from any further aspects of the study.

- *Pressure Pain Testing during MRI*: While lying in the MRI scanner, you may stop the pressure test at any time by speaking with the investigators.

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**.**

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 information from this study may benefit other people now or in the future.

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. OTHER OPTIONS

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

Taking part in this study is voluntary. You have the right to choose not to take part in the study. Ask the researchers or your regular doctors about other treatment options if you decide not to take part in the 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?

No. You may leave the study at any time without penalty or danger to yourself or others. If you decide to take part in the study, you can later change your mind and you are free to withdraw from the study at any time.

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 all research-related items and services that are provided 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 researchers' 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.

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?

Fibromyalgia participants may receive up to $390:

- $20 for completing the screening visit
- $10 for each acupuncture session
- $10 for completing and returning the Food Frequency Questionnaire
- $140 each evaluation (behavioral session, plus scan)

Control participants will receive $20 for completing the screening visit and $140 for their participation in the behavioral and scanning sessions.

All research subjects receiving payment for any study participation at the University of Michigan that exceeds $600 per calendar year must report this as income to the IRS.

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

Dr. Harte and Dr. Clauw, along with the University of Michigan, have an interest in one of the pain testers being used in this study. In future they may receive part of the profit from any sales of this device.

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 your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records only by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor (National Center for Complementary and Alternative Medicine), or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.] may review your research records.

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 kept in your study file until after 7 years or until the study findings are published, whichever is longer. They will then be destroyed.

9.2 What information 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. Information 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.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information

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 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.

A description of this clinical trial is available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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

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 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).

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:	Richard Harris, PhD
Mailing Address:	Chronic Pain and Fatigue Research Center 24 Frank Lloyd Wright Drive, PO Box 385 Ann Arbor, Michigan 48104
Telephone:	734-998-6996
Study Coordinator:	Kathy Scott
Mailing Address:	Chronic Pain and Fatigue Research Center 24 Frank Lloyd Wright Drive, PO Box 385 Ann Arbor, Michigan 48104
Telephone:	734-998-7022
Email:	jrsj@med.umich.edu

You may also express a 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: US Country Code: 001)
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 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

Authorization for Use of MRI images for Future Research

You are being asked to contribute some of your brain images and basic information (age, gender, diagnosis) for future research. In addition to being analyzed in this study, your images will also be submitted to the Pain and Interoception Imaging Network (PAIN) at the Center for Neurobiology of Stress, University of California Los Angeles. The PAIN initiative is funded PAIN is supported in part by NIH grants: P50 DK064539, R01 DK048351, U01 DK082370 and by the Gerald Oppenheimer Foundation. Data you donate will be coded, meaning all identifiable information will be removed and give a unique identification number so that you cannot be directly identified. The code will be kept in a secure location, which can only be accessed by the research team at the University of Michigan. The pain study team does not work for the institutional repository but has agreed to help collect data from research participants with their permission.

The choice to donate these images and data is up to you. No matter what you decide, it will not affect your medical care. It will also not affect your participation in other research studies including the study described in the attached pain study consent document. If you agree to take part in the PAIN repository and donate your images and data, you can change your mind at any time. Just contact the study team members listed in Section 10.1 and any future brain images and data will not be donated to the repository. *Please note* that any images and data collected from previously completed MRI scans cannot be withdrawn, but will remain de-identified.

Participating in the PAIN repository involves no additional time commitment. You will not receive any direct benefit from donating your images and related data to be stored indefinitely in the PAIN repository. The greatest risk to you from participating in the institutional repository is a breach of confidentiality, but this risk is small. More information about the risks and potential benefits of specimen and genetic research is provided in this study consent.

Research Subject:

Please check and initial your response to the following question:

I AGREE to donate the brain images collected during my MRI scans and related coded health information to the Pain and Interoception Imaging Network (PAIN) repository. There it may be used in future research to learn about, prevent or treat pain or other related health problems (for example: fibromyalgia, arthritis, irritable bowel syndrome, etc.).

Yes ☐ ***No*** ☐ ***Participant Initials*** _____

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.

Legal Name: _____

Signature: _____

Date of Signature: _____

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.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature: _____