

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:

Developing Biomarkers for Fibromyalgia

1.2 Company or agency sponsoring the study:

Department of Defense

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

PI: Richard E. Harris, Ph.D.; Research Instructor, Int Med-Rheumatology, University of Michigan

Co-I: Jon-Kar Zubieta, M.D., Ph.D.; Associate Professor, Dept. of Radiology/Dept. Psychiatry, University of Michigan

Co-I: Daniel J. Clauw, M.D.; Professor Medicine, Dept. of Internal Medicine-Rheumatology, University of Michigan

Co-I: Richard H. Gracely, Ph.D.; Professor, Dept. of Internal Medicine-Rheumatology, University of Michigan

Co-I: Pia Maly-Sundgren, M.D., Ph.D. Associate Professor in the Department of Radiology at the University of Michigan.

Co-I: Ananda Sen, Ph.D. Assistant Professor of Industrial Operations at the University of Michigan College of Engineering and Associate Professor of Statistics at the College of LSA at the University of Michigan.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this research study is to use brain imaging to identify an objective biological marker (a measurable sign in your body) for Fibromyalgia.

Further, we would like to review &/or analyze the information we collected about you during your Subject Registry visit (IRB #2002-0678, GCRC 1914).

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?

To take part in the study, Fibromyalgia subjects must: 1) meet established criteria for the diagnosis of fibromyalgia (FM) as defined by the American College of Rheumatology in 1990 for at least 1 year (The criteria for FM include presence of widespread pain in the following areas: above and below the waist, on both sides of the body, and in the neck, back, or chest. Additionally, criteria include the presence of 11 of 18 tender points in specified areas.); 2) have continued presence of pain more than 50% of days; 3) be able to travel to the acupuncture treatments up to three times weekly; 4) be willing to limit beginning any new medications or treatments to control FM symptoms during the study; 5) be between the ages of 18 and 75; 6) be right-handed; 7) refrain from alcohol intake 48 hours prior to brain scans; and 8) be capable of giving written informed consent.

Subjects who are healthy volunteers may also be enrolled in the study. Healthy volunteers must be: 1) between the ages of 18 and 75; 2) willing to refrain from alcohol intake 48 hours prior to brain scans; 3) right-handed; and 4) capable of giving written informed consent.

The exclusion criteria for the Fibromyalgia volunteers are: 1) having enough knowledge of acupuncture that prevents "masking" or "blinding" of the study interventions (i.e., previous acupuncture treatment); 2) presence of a known blood clotting defect (e.g., low platelets or bleeding disorder) that may prevent the safe use of acupuncture; 3) presence of concurrent autoimmune or inflammatory disease (e.g., rheumatoid arthritis, systemic lupus erythematosus, inflammatory bowel disease, etc.) that causes pain; 4) routine daily use of narcotic pain medications or history of substance abuse; 5) concurrent participation in other research trials; 6) pregnant and/or nursing women; 7) severe psychiatric illnesses (e.g., current schizophrenia, major depression with suicidal ideation, substance abuse within two years); 8) presence of current major depression that is assessed at your first study visit; 9) factors that would make positron emission tomography brain scans inadvisable, such as repeated exposure over the last 2 years to diagnostic x-rays, CT scan or nuclear medicine scans; 10) any impairment, activity or situation that, in the judgment of the Study Coordinator or PI, would prevent satisfactory completion of the study protocol.

The exclusion criteria for the healthy volunteers are: 1) presence of concurrent autoimmune or inflammatory disease (e.g., rheumatoid arthritis, systemic lupus erythematosus, inflammatory bowel disease, etc.) that causes pain; 2) having met the ACR criteria for Fibromyalgia; 3) concurrent participation in other research trials; 4) pregnant and/or nursing women; 5) severe psychiatric illnesses (e.g., current schizophrenia, major depression with suicidal ideation, substance abuse within two years); 6) factors that would make positron emission tomography (PET) inadvisable such as repeated exposure over the last 2 years to diagnostic x-rays, CT scan or nuclear medicine scans ; 7) any impairment, activity or situation that, in the judgment of the Study Coordinator or PI, would prevent satisfactory completion of the study protocol.

*Note: it is **very important** for you to give the researchers **accurate** and **complete** information about your medical history and condition.*

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

Total number of subjects is 60 - all will be studied at the University of Michigan and all will either have a diagnosis of FM upon entry into the study or will meet the criteria for a Healthy Volunteer

4. INFORMATION ABOUT STUDY PARTICIPATION

This consent is for the optional positron emission tomography (PET) part of this investigation.

4.1 What will happen to me in this study?

If you are meet the criteria for the Fibromyalgia group and agree to participate in this study, you will:

- have blood drawn for the testing of hormonal levels and genetic factors (genetic factors optional). The blood draw for hormonal levels will occur during the follicular phase of your menstrual cycle if you have not reached menopause. Approximately one tablespoon of blood will be drawn for the measurement of hormonal levels. If you consent to participate in the genetic part of the study, a blood sample will be obtained which will be used for genetic research (to examine the composition of some of the genes in your DNA). This aspect of the study will help to identify different forms of genes that may be associated with chronic pain (Fibromyalgia) and with variations in how people respond to acupuncture or pain. If you choose to participate in the genetic portion of the study, you will have approximately 3 tablespoons of blood drawn. There is no commercial use for the genetic material we will obtain from you. However, future studies may identify gene(s) that are involved in either acupuncture and/or pain. As such, we may use your genetic sample in future investigations of acupuncture and/or pain.
- have two Positron Emission Tomography (PET) images taken from your brain. PET is a type of body scanning that involves radiation in the form of injected “tracer” substances containing minute amounts of radioactivity. It allows the investigators to evaluate the function of your brain, and may require as long as 90 minutes to perform per scan, but waiting time and sometimes delays may take up to three hours of your time. A total of two identical scans will be performed,

one at the beginning of the study during your first acupuncture session and once during your final acupuncture session. These two days will be approximately one month apart. The PET procedures involved are outlined below.

- a) You will be asked to lie quietly without movement on a cot with your head located within the PET scanner.
 - b) To permit tracer injection and withdrawal of appropriate blood samples for completion of this procedure, a catheter (tube for withdrawing or introducing fluids) will be inserted into a vein of your arm for the injection of the radiotracer. If you are female and consent to it, your blood will be drawn from this catheter to measure your estrogen and progesterone levels. The total volume of blood to be removed per PET scan is 1-2 tablespoons.
 - c) The compound [^{11}C]carfentanil is a radioactively labeled tracer that binds to receptors involved in the control of pain, among other functions. Very small amounts of this radioactively labeled tracer will be injected into your vein followed by imaging with the PET scanner. A total of two PET scans will be completed on two separate days.
 - d) Each one of the PET scans will include two conditions: (a) a period of rest for baseline measurements and (b) period of either acupuncture or control condition.
 - e) During the scan, starting 5 minutes after the radiotracer is introduced, you will be resting for 30-35 minutes. After that time, the second condition (either acupuncture or control) will be initiated and again maintained for 30-50 min. We will be scanning during all this time for a total scanning time of 90 min. In this manner, we will study your brain function before and during each intervention. All supplies used are sterile, disposable and have not been in contact with any other person.
- be asked questions regarding the overall quality and intensity of your pain, as well as how you felt as you underwent the study. These questionnaires and rating scales will be collected at your scanning visit(s).
 - have a urine pregnancy test prior to each PET scan.

If you meet the criteria for the Healthy Volunteer group and enter this study, you will:

- have blood drawn for the testing of hormonal levels and genetic factors (genetic factors optional). The blood draw for hormonal levels will occur during the follicular phase of your menstrual cycle if you have not reached menopause. Approximately one tablespoon of blood will be drawn for the measurement of hormonal levels. If you consent to participate in the genetic part of the study, a blood sample will be obtained which will be used for genetic research (to examine the composition of some of the genes in your DNA). This aspect of the study will help to identify different forms of genes that may be associated with variations in how people respond to acupuncture or pain. If you choose to participate in the genetic portion of the study, you will have approximately 3 tablespoons of blood drawn. There is no commercial use for the genetic material we will obtain from you. However, future studies may identify gene(s) that are involved in either acupuncture and/or pain. As such, we may use your genetic sample in future investigations of acupuncture and/or pain.

- have one Positron Emission Tomography (PET) image taken from your brain. PET is a type of body scanning that involves radiation in the form of injected “tracer” substances containing minute amounts of radioactivity. It allows the investigators to evaluate the function of your brain, and may require as long as 90 minutes to perform per scan, but waiting time and sometimes delays may take up to three hours of your time. The PET procedures involved are outlined below.
 - a) You will be asked to lie quietly without movement on a cot with your head located within the PET scanner.
 - b) To permit tracer injection and withdrawal of appropriate blood samples for completion of this procedure, a catheter (tube for withdrawing or introducing fluids) will be inserted into a vein of your arm for the injection of the radiotracer. If you consent to it, your blood will be drawn from this catheter to measure your estrogen, progesterone levels. The total volume of blood to be removed per PET scan is 1-2 tablespoons.
 - c) The compound [¹¹C]carfentanil is a radioactively labeled tracer that binds to receptors involved in the control of pain, among other functions. Very small amounts of this radioactively labeled tracer will be injected into your vein followed by imaging with the PET scanner. A total of two PET scans will be completed on two separate days.
 - d) Starting 5 minutes after the radiotracer is introduced, you will be resting for 90 minutes; your brain will be scanned during this time.
- have a urine pregnancy test prior to each PET scan.
- be asked questions regarding the overall quality and intensity of your pain, as well as how you felt as you undergo the scan. These questionnaires and rating scales will be collected at your scanning visit.

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

Total participation time for Fibromyalgia patients is 6 hours over two days that are 4 weeks apart. Your initial PET scan will occur during the week following your initial interview and baseline (a measurement to serve as the basis to compare later measurements) at the University of Michigan Medical Center. This scan will take approximately 3 hours, of which 90 minutes will be spent in the scanner. During this scan you will receive an acupuncture intervention. You will also have a blood sample taken to measure different hormone levels (1-2 tablespoons) if you are female. Following the PET scan you will receive 7 acupuncture treatments over the course of a month. Each acupuncture session will occur at Domino’s Farms Lobby M, 24 Frank Lloyd Wright Dr., Ann Arbor MI. Your last PET scan will occur following the treatments and will be identical to your first PET scan; during this scan you will receive an acupuncture/sham intervention and you will be asked to complete questionnaires throughout the scanning procedures.

Your study participation concludes after the study close-out visit, approximately 3 weeks following your last study scan or 8 weeks following your enrollment into the study.

Total participation time for Healthy Volunteers spans 1 day and approximately 4 ½ hours. Following the consent process, you will have a PET scan which will last approximately 3 hours, 90 minutes of which will be spent in the scanner. You will not undergo any acupuncture/sham treatment during your PET scan.

4.3 When will my participation in the study be over?

As a Fibromyalgia participant, your PET participation concludes following your second PET scan.

As a healthy participant, your study participation concludes following your PET scan.

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 for people participating in the study include:

- Acupuncture: 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.
- PET Imaging:
 - Radioactivity is an essential part of this study. The radiation dose that you will receive from each PET procedure is in the range of doses received from routine diagnostic studies. The effective dose and risk of this level of exposure is less than 1/2 that from a CT exam (CAT scan) of the chest. The biological effect of radiation is measured in terms of Roentgen equivalents in man, or “rem”, which is a unit of uniform whole body exposure. Radiation you will be exposed to in this study will amount to 0.3 rem per PET scan, which is 6% of the dose that occupationally exposed individuals are permitted to receive each year. You will be exposed to a maximum of 0.6 rems if both PET scans are completed, which is 12% of the dose that occupationally exposed individuals (like x-ray technicians) are permitted to receive each year. This total dose of radiation is slightly higher than that associated with a CT scan of the chest. The effects on your body of this radiation exposure will be added to your overall lifetime radiation risk. Your lifetime radiation risk includes the background radiation you are exposed to naturally, like everyone else living on this planet, which is on the average 0.3 rem per year. The maximum amount of radiation per each PET scan that you will be exposed to in this study is about the same as the yearly background radiation, and it will be twice that if both scans are completed. The risk from radiation exposure of this amount is considered to be similar to other every day risks, such as driving a car. Your lifetime radiation risk also includes any radiation you may have received in the past for diagnosis or treatment, and any such radiation you may be exposed to in the future. Please tell us if you have had any major radiation exposure in the past, particularly in the past two years, such as treatment with x-rays or radioactivity, or diagnostic x-rays, CT-scans or nuclear medicine scans.
 - Although venous catheterizations are safe procedures, there is a small chance that the puncture may result in pain, unexpected bleeding, clotting, infection or constriction of the vein. If a clot forms, this may require medical or surgical treatment. Withdrawing blood may also induce lightheadedness or fainting.
 - Although unlikely at the very small, tracer dose used in this study, an allergic reaction to the drug used for PET imaging (carfentani) is possible. This would require medical

treatment. Please let us know if you are allergic to medications, particularly opiate drugs such as morphine or fentanyl, since carfentanil is derived from them. Subjects who are particularly sensitive to opioid drugs may experience mild dizziness or nausea even with the very small amounts of carfentanil administered during the PET scans.

- You may experience some discomfort or pain while lying in one position in the PET scanner.
- Genetic Testing: Information about your race, ethnicity, sex, and medical history might be available for investigators studying your blood. Such information is important for scientific context and sometimes for public health and it is possible that genetic information might come to be associated with your racial or ethnic group. Genetic research raises difficult issues about informing you and other subjects about any results or of future results. Some people want to know what is found out about them, others do not. We do not anticipate that our findings will be useful for any individual subject. Therefore, we will not inform you about any results, and you agree that: 1) you waive the right to consent to or be notified of any future research, test or analysis which might be performed using blood samples, and 2) you waive the right to any results or information generated by future tests or analyses using blood samples and assign any such rights to the University of Michigan. Your sample will not be stored for future genetic testing for either yourself or other family members. If you are interested in storage of a blood sample for genetic testing, you should consult with a clinician skilled in this area. In addition, there is no commercial use for the genetic material we will obtain from you. However future studies may identify gene(s) that are involved in either acupuncture and/or pain. As such, we may use your genetic sample in future investigations of acupuncture and/or pain.
- Blood draw: Withdrawal of blood from your arm veins for genetic testing and hormonal levels (if you are female) is optional. There is a small chance of pain, infection or clotting into the area from which the blood was taken; more rarely, serious skin infections or nausea and vomiting may occur. If persisting pain or redness in the area is noted, this may require medical or surgical treatment. Withdrawing blood may also induce lightheadedness or fainting.

The researchers will try to minimize these risks by:

- Acupuncture: All risks will be minimized with 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. An experienced 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.
- PET Imaging:
 - We will ask you if you have had any major radiation exposure in the past, particularly in the past two years such as treatment with x-rays or radioactivity or diagnostic x-rays, CT-scans or nuclear medicine scans. This will help assess your radiation risks.
 - These scans are performed in a medical setting by highly trained and qualified personnel to reduce the possibility of risk to you.

- After each PET scan we will ask you to drink several glasses of water which will reduce the radiation exposure to your kidneys and bladder.
- To minimize the possibility of nausea, we will ask you not to eat solid foods for at least 2 hours prior to the PET scans.
- We will provide pads and blankets to make you as comfortable as possible while lying in the scanner.
- We will ask you about any drug allergies that may affect your ability to have a PET scan.
- If you experience any sort of discomfort during the PET procedure at any time, you can stop the scan. You will be able to talk to us throughout the procedure, and you will be able let us know right away if you want to stop the procedure and get out of the scanner. You will be able to end the pain testing session at any time by saying 'Stop'. The investigators will be present at all times.
- If you are a female of childbearing potential, you will be required to use an appropriate and effective method of birth control during your participation in this study given the risk of radiation to the fetus. These methods may be discussed with your physician. Women of childbearing potential will be required to take a urine pregnancy test the day of fMRI and PET testing. If you do not wish to take the pregnancy test, you will be excluded from any further aspects of the study.
- Questionnaires: You may refuse to answer any question on the questionnaires or surveys.
- Data Collection: As mentioned in Section 9.3 of this consent form, we will not identify data collected during your participation in this study with personal identifying information. Data collected during this study will be kept either in a locked file cabinet or a password-protected database. In addition, your genetic sample will not be able to be identified with you personally.
- Genetic Testing: In order to protect you from potential risks of genetic testing we will,
 - store your blood under a unique identifying code for this study and it will become anonymous, i.e. not linkable to a person, after completion of the study.
 - protect your confidentiality to the extent permitted by law. Samples will be coded and the code will be stored at a locked location. The University of Michigan collaborates with many other organizations, and data are generally shared. However, no data shared with other investigators will include your name or other information that would allow anyone to know who you are.
 - inform you that you have the right to refuse to allow your blood to be studied or saved for future research (i.e. not to participate in the genetic study or to withdraw from it). You may withdraw from this part of the study at any time, and withdraw from research use of your sample. However once your sample has become anonymous, even if you choose to withdraw your sample the researchers will not be able to identify which sample is yours.
 - In addition, information about your race, ethnicity, sex, and medical history might be available for investigators studying your blood. Such information is important for scientific context and sometimes for public health. It is possible that genetic information might come to be associated with your racial or ethnic group.
 - Genetic research raises difficult issues about informing you and other subjects about any results or of future results. Some people want to know what is found out about them, others do not. We do not anticipate that our findings will be useful for any individual

subject. Therefore, we will not inform you about any results, and you agree that: 1) you waive the right to consent to or be notified of any future research, test or analysis which might be performed using blood samples, and 2) you waive the right to any results or information generated by future tests or analyses using blood samples and assign any such rights to the University of Michigan.

- Your blood will not be stored for future genetic testing for either yourself or other family members. If you are interested in storage of a blood sample for genetic testing, you should consult with a clinician skilled in this area. No results will be released to participants or to their representatives, and blood collection data will be retained for five years after study termination. You may withdraw from this part of the study at any time and withdraw from research use of your sample.
- **Blood drawing:** Only individuals skilled in the process of blood drawing will be used to take your blood sample. Pressure will be applied to the site to reduce the risk of bruising. Sterile technique will be used to reduce the risk of infection.

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.

Because this research is funded by the U.S. Army, the following is available to you:

Subjects who are injured as a direct result of this research study are eligible to receive medical care at any Army hospital or clinic free of charge. The Army will not pay for your transportation to or from the hospital or clinic. Subjects who pay out-of-pocket for medical care elsewhere for injuries caused by this research study should contact the principal investigator (Richard E. Harris, Ph.D., (734) 998-6996) . If the issue cannot be resolved, contact the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301) 619-7663/2221.

Dr. Sawsan As-Sanie will serve as the Medical Monitor for this study and in addition to the study personnel knowing how to contact Dr. As-Sanie, you will be able to contact Dr. As-Sanie via phone at 734-764-8429. In the case of an adverse or serious adverse event that may be study related please call Dr. As-Sanie at the above number.

Adverse experiences that are both serious and unexpected will be immediately reported by telephone to the UM IRB and the USAMRMC, Office of Research Protection, and followed by a written report.

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 nor will you be informed of any specific research results. However, it is possible that you may experience a reduction or elimination of symptoms due to acupuncture. The potential indirect benefits of this research to the public or others include a greater acceptance of acupuncture to the general population. Better management of FM symptoms may also result from this study.

The type of scans we will use are not very sensitive to many abnormalities. The scanning procedures used for this study will not be read by a specialist trained to make medical diagnoses from the scan. That is, even if there is an abnormality in your body, it is likely that it would not be discovered by the people who inspect the images. Therefore, it is likely that any abnormality that you may currently have will not be revealed by the images obtained in this experiment. If you have any current health concerns, you should consult your doctor.

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?

Your participation is voluntary. Should you decide not to be in the study, there are options if you need treatment: routine medical care for FM consists of some combination of medications (prescribed based on your symptoms and level of tolerance), exercise, and physical therapy. None of these treatments are included in this study.

Ask the researchers or your doctor about other choices you may have.

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” (below).

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

You may exit the study at any time without any penalty or danger to yourself or others. There are no exit interviews or tests to perform. By leaving early, you will receive no further study-related procedures of any kind. You will receive compensation for the portion of the study that you have completed.

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 choose to participate in this study you will not be reimbursed for traveling expenses such as gas and mileage, however parking will be free of charge. Neither you nor your insurance company will be billed for any study-related costs, including acupuncture supplies, office visits to the acupuncturist, and PET scans. If you are not sure what these covered items 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. If your regular doctor orders a PET scan for your routine care while you are taking part in the research study, it will be billed to you or your insurance. This PET scan will not have anything to do with the research and will be totally separate from the PET scan you will need for this research study.
- Monitoring for side effects or other problems related to your fibromyalgia, but not due to the research study
- Treatment of complications related to your fibromyalgia, but not due to the research study
- 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?

Yes. You will be compensated \$150 per PET scan for the time spent in participation in the study, upon completion of each scan. There may be additional compensation to you when you participate in the other scanning procedure (fMRI) in this study. Employees of the University of Michigan will have their study compensation added to their regular paycheck.

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

No person or organization has a financial interest in the outcome of this study.

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?

We shall put the information collected about you during the study into a research record. This research record will not show your name, but will have codes entered into it, that will allow the information to be linked to you. However, we shall keep your research record confidential, to the extent provided by federal, state and local law. Research records will be kept in a separate research file that does not include names, registration numbers or other information that is likely to allow someone other than the

researchers to link the information to you. We shall not allow anyone to see your record, other than people who have a right to see it. You will not be identified in any reports on this study.

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.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Your AIDS/HIV status
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing 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.
- U.S. Department of Defense and representatives of the U.S. Army Medical Research and Materiel Command are eligible to review subject records as part of their responsibility to protect human subjects in research.

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?

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.med.umich.edu/hipaa/npp.htm>. 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).

When you sign this consent form, you have agreed that researchers may use limited information (excluding your name, date of birth, address or social security number) about you in order to determine the significance of individual or group data that we collect in this research study. You may cancel this permission by submitting a written notification to the principle investigator listed below.

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: University of Michigan
Chronic Pain and Fatigue Center
24 Frank Lloyd Wright Drive P.O. Box 385
Ann Arbor, MI 48106
Telephone: 734-998-6996

Study Coordinator: Laura Mayo-Bond
Mailing Address: University of Michigan
Chronic Pain and Fatigue Center
24 Frank Lloyd Wright Drive P.O. Box 385
Ann Arbor, MI 48106
Telephone: 734-998-7045

You may also express a concern about a study by contacting the Institutional Review Board listed below, or by calling the University of Michigan Compliance Help Line at 1-888-296-2481.

University of Michigan Medical School Institutional Review Board (IRBMED)

Argus I
517 W. William
Ann Arbor, MI 48103-4943

Telephone: 734-763-4768
Fax: 734-615-1622
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481.

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.) (In addition, a copy of this freshly-signed and dated consent form will be kept on file at the PET lab.)*
- Other (specify): _____

12. SIGNATURES

Research Subject:

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 for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study. I give permission to review &/or analyze information collected in my participation in the project, "Subject Registry," 2002-0678.

If you consent to participate in the genetic part of this study, a blood sample will be obtained which will be used for genetic research (to examine the composition of some of the genes in your DNA). This may help to identify different forms of genes that may be associated with chronic pain (Fibromyalgia) and with variations in how people respond to acupuncture or pain. We do not anticipate that our findings will be useful for any individual subject. Our interest in this study is to identify genes that are responsible for developing wide-spread pain (Fibromyalgia) and genes that may identify responsiveness to Acupuncture. The testing in this study is not going to include testing for any genes that are known to predict the risk of developing any specific disease. If you choose to participate in the genetic portion of the study, you will have approximately 3 tablespoons of blood drawn. Since there is currently no accepted genetic test for fibromyalgia, the results of this testing will not be given to you. Information about your race, ethnicity, sex, medical history, and response to acupuncture from this study will be combined with the genetic information and put in a database for future research on genetic factors and fibromyalgia and chronic pain. Your sample will not be stored for future genetic testing for either yourself or other family members. If you are interested in storage of a blood sample for future genetic testing, you should consult with a doctor who knows how to do this. Information linking you to the blood sample will be kept until the research study is completed. Once the research study is over, all links to any identifying information will be destroyed, so it will not be possible to identify who a blood sample belongs to. You can withdraw your permission to use the genetic sample for research before the research study is completed by contacting the study team using the information that has been given to you in Section 10 of this form. However, once the research study is over, it will no longer be possible to identify which genetic sample is yours.

I agree to have my blood used for genetic testing if it was obtained during Subject Registry, or during this current study.

I do not give authorization to have my blood withdrawn now or used from the Subject Registry for genetic testing.

I give permission for information collected about me in an earlier research study involving Acupuncture (2004-0526) to be analyzed within this current research study (HUM0010061).

I do *not* give permission for information collected about me in an earlier research study involving Acupuncture (2004-0526) to be analyzed within this current research study (HUM0010061).

Signature of Subject: _____	Date: _____
Name (Print legal name): _____	
Patient ID: _____	Date of Birth: _____

Legal Representative (if applicable): Signature of Person Legally Authorized to Give Consent _____	Date: _____
Name (Print legal name): _____	Phone: _____
Address: _____	
Check Relationship to Subject: <input type="checkbox"/> Parent <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Sibling <input type="checkbox"/> Legal Guardian <input type="checkbox"/> Other: _____	
<i><u>If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.</u></i>	
Reason subject is unable to sign for self: _____	

Principal Investigator (or Designee): <i>I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.</i>	
Name: _____	Title: _____
Signature: _____	Date of Signature: _____

Witness (optional):

I observed the above subject (or his/her legally authorized representative, if applicable) sign this consent document.

Name: _____

Signature: _____ Date of Signature: _____