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Protocol Title: Evaluating Specific and Non-Specific Mechanisms in Two Distinct Complementary/Integrative Interventions for Chronic Pain
Sponsor: NIH/NCCIH

Name of Participant: _____

RUSH

CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

Key Information about this research study

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future. You are being asked to participate in this study because you have chronic low back pain.

Taking part in this research study is voluntary

You do not have to participate in this study or may choose to leave the study at any time. If you decide not to participate in this study or leave the study later, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected. No promises can be made about the outcome of this as far as your current condition, either positive or negative.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information

This information gives you an overview of the study. More detailed information about the study will follow later in the document.

Why is this research being done?

- A goal of this study is to compare the effectiveness of Mindfulness Training (MT) to spinal manipulation therapy (SMT) in helping people with chronic low back pain reduce

pain and suffering.

- Another goal is to reveal the reasons why these kinds of treatments reduce pain and suffering.
- The study involves a psychosocial treatment (MT) and a physical therapy (SMT).

If you participate, how long will the study last?

Your participation in this study may last up to 8.5 months. There will be a total of 14 study visits. There will be 4 laboratory sessions lasting up to 3.5 hours each, 8 therapy sessions lasting 1 hour each, and two follow-up visits (3 months and 6 months) after you have completed the 8th therapy session and the final laboratory session.

What will happen to you during the study?

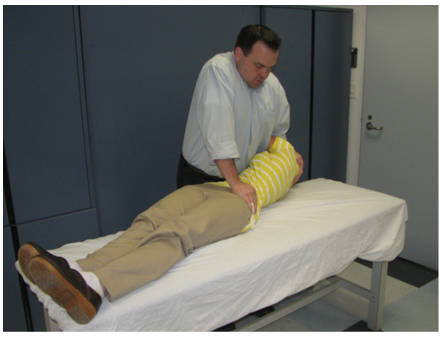
If you are eligible, you will be randomly assigned (like flipping a coin) to either the MT or SMT treatments.

For the laboratory sessions, you will undergo acute pain induction procedures while you are given a placebo or naloxone. Naloxone is approved by the Food and Drug Administration (FDA) as an opioid antagonist that has been used clinically for decades for treatment of opiate overdose and for reversal of surgical anesthesia. In this study Naloxone is being given for research purposes only. While participating in this study, you will receive naloxone during two laboratory sessions and you will receive placebo during two laboratory sessions. These sessions will be scheduled 3 days apart at each assessment point (pre-and post-intervention).

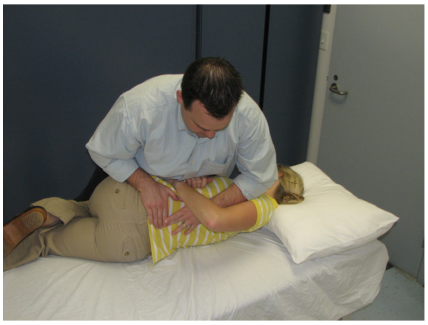
You will participate in eight (1-1.5 hour) MT or SMT therapy sessions. The first four will occur in consecutive weeks, followed by 2 mid-therapy laboratory sessions. The final therapy sessions will occur after the mid-therapy sessions and also be conducted in 4 consecutive weeks. Before and after each session for subjects in both the MT and SMT treatments, you will have your spinal stiffness assessed with a VerteTrack device. Within 24 hours of each session, a Research Assistant will contact you via phone, and conduct post-session assessments. You will also attend a brief visit at 3-mos and 6-mos post-treatment to complete questionnaires.

MT will involve helping you recognize how certain reactions to stress and pain may worsen your pain and suffering. This treatment will help you to better recognize stressful events, like pain, and to physically relax in order to better cope (deal with things).

SMT will involve correcting out of line spinal joints through the application of specific procedures by the therapist in order to restore normal spinal movement. Two procedures will be used. In the first one, the therapist will place their hand on the front of your pelvis on your hip bone. They will give a small downward thrust to that bone. See illustration below:



During the second procedure, you will lie on your side. The therapist will then position your body for the intervention. He/she will place their hands on your low back and their elbow on the back of your pelvis on your hip bone. He/she will give a small forward thrust to that bone. See illustration below.



The final procedure is the pelvic tilt exercise. You will be asked to lie on your back, bend your needs so that your feet are flat on the surface, and you will press the small of your back to the table to create a pelvic tilt. See illustration below.

For more information, please see the "*What are the activities you will be doing if you participate in this study?"* section below.

Is there any risk to you in participating in this study?

Taking part in this study may expose you to some risks. We may not know or understand all the risks at this time. Some people may experience side effects or discomfort. It is very important that you understand the known risks in this research study before you decide whether to participate. For details and a list of risks you should know about, please see the "*What are the risks and discomforts of participating in this study?"* section below.

Will you benefit from the study?

You may benefit from taking part in this study, but there is no guarantee that it will help you. For more information, please see the *"What are the benefits of participating in the study"?* section below.

Do you have other options besides taking part in this study?

The only alternative to participating in this study is not to participate.

Will you be paid to participate in this study?

Payment for your time or travel is available if you decide to take part in this study. For more information, please see the "*Will you be paid for your participation in this study?"* section below.

Will it cost you anything to participate in this study?

There is no cost to you for taking part in this study.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this study.

General Information

You are being asked to participate in this study because:

1) You have significant daily chronic pain intensity (at least 4 on a 10-point scale) and interference in performing daily activities due to pain (at least 3 on a 10-point scale) for at least 3 months;
2) You have musculoskeletal pain of the low back and/or leg pain that may be related to history of degenerative disk disease, spinal stenosis, or disk herniation (radiculopathy subcategory), or muscular or ligamentous strain (chronic myofascial pain subcategory);
3) You are between the ages of 18 and 75 years.

You may not take part in this study if:
1) You meet criteria for alcohol or substance abuse problems;
2) You meet criteria for past or present psychotic or bipolar disorders;
3) You are not able to understand English well enough to complete questionnaires or to participate in treatment;
4) You have active suicidal ideation with intent;
5) Your pain is due to malignant conditions (such as: cancer, rheumatoid arthritis), migraine or tension headache, fibromyalgia or complex regional pain syndrome.
6) You are pregnant or breastfeeding.
7) You are in ongoing psychosocial treatment of any duration (CBT, mindfulness) or ongoing physical or manipulation therapy (PT, chiropractic, etc.).
8) You have had lumbar surgery within the past 6 months.
9) You have a liver disease such as hepatitis or cirrhosis
10) You have osteoporosis/osteopenia or bone demineralization
11) You have an opioid dependency
12) You cannot hold your breath for 15 seconds
13) You have an acute trauma to your spine
14) You have long term use of corticosteroids
15) You have a spinal cord stimulator, an IT pump, or a similar device
16) You have a BMI of ≥40 or a waist measurement of 8.5-9.5 inches or greater from abdomen to back

How many people will take part in this study?

Approximately 240 participants are expected to take part in this study at Rush University Medical Center and Vanderbilt University Medical Center.

What are the activities you will be doing if you participate in this study?

If you agree to be in this study, you will be asked to participate in the following activities.

COVID-19 PRECAUTIONS BEFORE EACH STUDY VISIT

- Due to the COVID-19 pandemic (also known as the coronavirus), you must wear a face mask when you come to Rush for your study visits. No exceptions. Rush approved face masks will be provided to you once you enter the building or when you are checking in for your visit. Your temperature will also be taken once you enter a Rush building. You will also be asked to self-screen for signs/symptoms of COVID-19 **before** coming to your visit and we will ask you these questions again when you arrive. If you are showing any signs/symptoms, you will be asked to reschedule your study visit. Study staff reserves the right to reschedule your appointment if they think you may be showing signs/symptoms of COVID-19. We may continuously have additional screenings for you if there are any changes from the Chicago Public Health Department and/or Rush policies.

You will need to inform the study staff about all medications (including prescription, over-the-counter, herbal, or even illegal) that you are currently taking. You will only be allowed to participate in this study if you are not taking opioid pain medications on a daily basis (for example, Morphine, Oxycontin, Tylenol #3, Vicodin, Ultram). This is because individuals who take opioid pain medications daily or who are dependent on prescribed or non-prescribed opiate medications (including heroin) may experience side effects (such as sweating and nausea) when the study medication, naloxone, is administered. Naloxone is approved by the Food and Drug Administration (FDA) as an opioid antagonist that has been used clinically for decades for treatment of opiate overdose and for reversal of surgical anesthesia. In this study Naloxone is being given for research purposes only. You will receive naloxone during three laboratory sessions while participating in this study. Naloxone should have no noticeable side effects if you do not have a recent history of opioid dependence, and are not taking opioid medications on a daily basis. If you take opioid pain medications on an as-needed basis, you will be asked not to take any of these medications for 3 days before each laboratory session, in order to avoid altering your sensitivity to the experimental procedures used in the study (described below). You will also be asked not to take opioid pain medications for 24 hours after each session to avoid possible interactions with the medication used in this study.

To insure your safety, prior to each study session you will be asked to provide a urine sample to confirm that you have not taken opioid pain medications recently, and if you are female, to conduct a pregnancy test. You must test negative on both tests to participate.

Screening

You will first be asked to attend a baseline screening session during which you will undergo a screening to confirm that you are eligible to participate in the study, and complete several questionnaires. This will involve providing information on your pain condition, your medical history, medications you are taking, and a brief examination to document the nature of any chronic pain. You will also be asked to complete several questionnaires asking about general information (for example, age, gender, etc.), your activity and exercise levels, your chronic pain and how it affects your life, and psychological factors that can affect pain and responses to pain medications. These psychological factors include anger-related factors, depression, anxiety, and how you cope mentally with pain. Information obtained from these questionnaires will be used to help interpret the laboratory results of this study, and for guiding future related studies. For your safety, you must tell the study doctor or nurse about all the medications you are taking before you start the study and before taking any non-study medications while you are in the study.

General Procedure

You will be randomly assigned (selected by chance, like the roll of a dice) to participate in Mindfulness Training (MT) or Spinal Manipulation Therapy (SMT). For all participants, treatment will consist of 8 weekly, 1-1.5 hour sessions (more details below). The sessions will be individual (that is, just you and the therapist). We will ask you to complete questionnaires before you start treatment, 48 hours after each weekly session (a research assistant will phone you and

read you questionnaires or an online link will be sent to you), and at 3-month and 6- month in-person or virtual follow-up visit.

Laboratory Sessions

You will be asked to attend two laboratory sessions before you begin MT or SMT, and then again at post-treatment. Each group of 2-session laboratory procedures will be scheduled over an approximately 3-day period at the same time of day. You will receive an injection of either naloxone, or placebo [an inactive substance]). All laboratory sessions will each last about 3.5 hours or less. All laboratory procedures will be conducted while you are seated upright in a comfortable chair. Nursing staff (supervised by the study physicians) will be present during all procedures, and emergency medical supplies will be available on site. You will be asked about recent medication use, and if necessary, will be rescheduled. All study drugs will be administered by a trained clinical research center staff nurse under physician supervision. You will receive placebo during one of the sessions and naloxone (a temporary blocker of your body's natural opioids) during one of the sessions. You will have an equal likelihood of receiving the placebo, or the naloxone, with the order of medications determined using a procedure similar to flipping a coin. Both you and the research nurse will be unaware of the specific medication you have been assigned for each laboratory session, although this information will be available if necessary. Prior to beginning the first part of the laboratory study in session 1, you will undergo a standardized thermal (heat) pain task training test.
During each laboratory session, you will first complete a 5-minute seated rest. Then a venous cannula (plastic tube inserted into a vein [i.v.] like you might get in the hospital) will be placed in your nondominant arm by the research nurse. You will then complete a questionnaire to describe your current low back pain intensity. Naloxone or placebo in 20 ml normal saline will be infused over a 10-minute period through an intravenous cannula placed in the non-dominant arm. A second dose of naloxone (0.055 mg/kg; 4mg for a 160 lb individual) or placebo will be infused following the thermal and ischemic tasks (see below).

To enable potential future assessment of treatment-related changes in relevant biomarkers, a 4ml sample of whole blood will be drawn from the cannula placed for drug administration into a tube with ethylenediaminetetraacetic acid (EDTA) prior to beginning laboratory pain or drug administration procedures in laboratory sessions. Within 10 minutes of collection, samples will be centrifuged for 10 minutes at 3500 rpm and 4○C. Plasma will then be pipetted into microcentrifuge tubes (0.5mL aliquots) and stored at -80○C until assayed.

Ten minutes after each dose of medication is received (to allow peak drug activity to be achieved), you will be asked to complete a brief questionnaire to describe your chronic back pain intensity. Then, you will be asked to exercise your dominant hand for two minutes by squeezing a hand-grip exerciser. A blood pressure cuff will then be inflated on that arm (slightly higher than when you normally have your blood pressure taken). This level of inflation is not harmful, but will result in a slowly building "aching" pain in that arm (this task is called an "ischemic" pain task because it decreases blood flow temporarily). You will be asked to indicate when the sensation first becomes painful, and then indicate when you wish to stop the task (because you

have reached your maximum tolerance). This task will last a maximum of 5 minutes. At 30 second intervals during this task, you will be asked to rate the level of pain you are experiencing on a 0-100 scale, with 0 being "no pain" and 100 being the "worst possible pain." Following completion of this task, you will be asked to rate the quality and intensity of the pain you experienced using a questionnaire.

Next, you will undergo a thermal pain task to assess heat pain threshold and tolerance. This task will involve repeated brief applications of a computer-controlled heat stimulus to several areas of your non-dominant forearm. The equipment used in this task is safe and only produces heat at 127 degrees Fahrenheit or less, which is below the level that causes burns. You will be asked to participate in three brief heat stimulation trials during which you will be asked to indicate when the heat stimulus first becomes painful (your heat pain threshold), and three brief trials during which you will be asked to indicate when your heat pain tolerance has been reached. For each trial, as soon as your tolerance is reached, the equipment will rapidly cool your skin to normal body temperature, ending the pain stimulus. Immediately upon completion of the final heat pain tolerance trial, you will be asked to rate the quality and intensity of the pain you experienced, as well as any drug-related side effects.

Finally, you will participate in what is called a test for "conditioned pain modulation" (your ability to reduce the intensity of pain). This test will proceed as follows: You will be asked to participate in three brief thermal stimulation trials (just like above) during which you will be asked to indicate when the heat stimulus first becomes painful (your heat pain threshold), and three brief trials during which you will be asked to indicate when your heat pain tolerance has been reached. Then you will put your hand in ice-cold water for 30 seconds. Then, you will repeat the thermal simulation trials just like above.

Mindfulness Training (MT)

This treatment involves helping you recognize how certain reactions to stress and pain may worsen your pain and suffering. This treatment will help you to better recognize stressful events, like pain, and to physically relax in order to better cope (deal with things). You will receive MT through (a) body scan meditation, a gradual moving of attention through the body, accompanied by awareness of breathing and other bodily sensations while in a lying position, (b) sitting meditation, focusing on awareness of breathing, bodily sensations, thoughts, and emotions, practiced sitting on a chair or cushion, (c) gentle movement exercises intended to develop awareness (mindfulness) during movement. Each session includes practice of these mindfulness techniques. In-session teaching material, interactions and discussion of your experiences of developing and applying mindfulness in everyday life are also part of each session. In-session activities include suggestions for application of mindfulness as a method for responding positively to stress, dealing with the challenges of pain, and exercises focusing on the challenges and achievements you may experience in bringing mindfulness into your daily life. Finally, you will develop a written plan to keep your gains once treatment has ended.

Spinal Manipulation Therapy (SMT)

You will engage in two SMT techniques during each session. Each SMT session will occur as follows: 1) You will lie on the SMT table for 20 minutes, while the physical therapist (PT) waits nearby. The PT will review with you your eligibility criteria to make sure nothing changes from week to week. 2) The PT will perform the two SMT techniques on you during the next 20 minutes. 3) You will lie on the SMT table for the remaining 20 minutes while the PT sits nearby and be asked to perform a posterior pelvic tilt exercise.

For the first SMT technique, you will lie on the PT table with your hands clasped behind your head. The PT will bend you in one direction. The PT will then link his/her arm through yours and will rotate your back. The PT and you will maintain this position, and he/she will apply a fast but gentle thrust to your hip. Please see illustration above.

For the second SMT technique, you will lie on your side with the more painful side facing up. The PT will rotate your back and bend you by pulling on your lower arm. The PT will maintain this position and will then rolls you towards them. A quick, gentle thrust will then be applied to your pelvis. Please see the illustration above.

For the final pelvic tilt exercise, you will lie on your back, bend your knees so feet are flat on the surface. Then, you will be asked to flatten your back to the table by slightly drawing in your stomach and rotating your hips back. Please see the illustration above.

During this study, Dr. Burns and his study team will collect information about you for the purposes of this study.

Information about medical and psychiatric history. Information about your medical diagnoses relevant to your low back pain, age, medication usage will be collected to ensure your eligibility for this study. A brief interview regarding whether or not you have or had psychiatric and substance use disorders will be conducted to ensure your eligibility for this study.

Information about pain sensitivity. Information about your pain threshold and tolerance under placebo and naloxone will be collected. The main goal is to see whether your natural ability to reduce pain intensity changes over the course of the MT or SMT sessions.

Information about pain, mood and function. Information about your chronic pain intensity, mood state (how depressed, angry, or anxious you feel) and function (for example, your ability to work, participate in recreation activities). Information about how much support from family and friends you receive will also be collected. The main goal is to see whether these factors change (for example, your mood improves) over the course of the MT and SMT sessions.

Will you be contacted about studies in the future?

If you agree, we may contact you after your participation in this study to request additional information. Please initial one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?

You may find completing questionnaires regarding your pain and psychological state and mood (including thoughts of harming yourself) to be mildly distressing. This level of distress is likely to be similar to what would occur if you were discussing these issues with your physician or a family member. If it is discovered that you are a risk to yourself, a set of standard procedures will be followed by the study staff for your safety. These procedures may include escorting you to the Rush Emergency Department, or having you speak with the Principal Investigator (Dr. John Burns) about options for receiving proper care.

The MT and SMT sessions pose limited risks. However, we are collecting spinal stiffness measurements so you may find having your spinal mobility assessed during a computerized piece of equipment (which places a roller against your back while you are lying face down on an examination table) uncomfortable.
For MT, you may experience some distress when sharing personal information during the treatment sessions. Please note that all session material will be confidential. You may also begin to experience other discomforts that will not be addressed in the treatments. If so, you will be referred for additional individual treatment, although such treatment may not be free of charge. You may also feel uncomfortable because the sessions will be audio-recorded. Sessions are audio-recorded only so that study investigators (at the University of Massachusetts) can assure that you are receiving the correct and most accurate treatment. No identifying information about you will be included on the audio-recordings. No one outside the study staff will have access to the audio-recordings.

You may also not improve a lot with treatment. If so, and if you request other treatment, you will be referred for other treatment, although such treatment may not be free of charge.
For SMT, participation in this treatment does not increase the risk of physical injury above what is a normal risk for seeking treatment for low back pain from a physical therapist or chiropractor. You may experience an increase in your low back pain after a session. Any increase in pain is expected to return to normal within 5 minutes or so. Based on our experience, the chance of this happening is common, which means it occurs in 1% to 25% of people (1-25 out of 100). We have attempted to minimize this risk by using two SMT techniques for which reports of increased pain are unlikely.

You may also feel uncomfortable because the sessions will be video-recorded. Sessions are video-recorded only so that study investigators (at the University of Florida) can assure that you are receiving the correct and most accurate treatment. No identifying information about you will

be included on the video-recordings. No one outside the study staff will have access to the video-recordings.

The laboratory acute pain tasks pose limited risks.

You will experience brief, moderate intensity acute pain upon application of the ischemic and heat pain stimuli that will be used both for acute pain evaluation and assessment of your natural pain control systems. However, you have total control over the duration of your exposure to these pain stimuli because you may stop each task by indicating when you have reached your tolerance limit. Previous research indicates that these tasks are safe, but to further maximize safety, people experiencing cardiovascular (heart and blood vessel) problems will be excluded from this study. In addition, the device that generates the heat for the heat pain task can only produce heat up to 127 degrees Fahrenheit – which is well below the heat level that causes burns – and automatically shuts off if it reaches that temperature. Because you have total control over the duration of each task, its impact on your distress level is expected to be minimal.

You will experience very brief, mild pain upon insertion of a cannula (for study drug administration) during each study session. This event is similar to what you have likely experienced at some point during medical treatment when blood samples were drawn, or if you have ever received an IV while hospitalized. Insertion will be performed by a trained nurse or physician to minimize discomfort associated with insertion of the cannula. There is a risk of infection and local inflammation or bruising at the site of cannula insertion. Although rare, you may experience a burning sensation during the infusion. Precautions will be taken to insure that such risks are minimized.

The following risks relate to the medications to be used in the study. The medication used for opioid blockade, naloxone, has been used clinically for decades for treatment of opiate overdose and for reversal of surgical anesthesia. It is not an experimental or new drug and is FDA-approved. Previous studies indicate that it is safe for individuals who are not opiate dependent, do not have liver disease, and do not have cardiovascular problems. Potential subjects experiencing these types of problems will be excluded from this study to insure a maximal level of safety with drug administration. Individuals taking daily opiates, even if not dependent, will also be excluded from the study to avoid causing minor withdrawal symptoms. In some individuals, naloxone may increase pain sensitivity to the acute pain tasks somewhat, but again, you may stop these tasks if you reach your tolerance limit. Based on previous studies, naloxone is expected to have limited if any direct effects on your back pain intensity, and therefore, there appears to be little risk of worsening your chronic pain condition. Even if such changes do occur, the brief half-life of naloxone (on average, approximately 45-60 minutes) would result in that any worsening pain will be of short duration. With the exception of possible effects on pain sensitivity, naloxone is not known to be associated with other clinically significant effects in healthy individuals who are not opiate dependent or using daily opiates.

There may be other risks that may happen that we cannot predict.

What are the reproductive risks of participating in this study?

Women

If you are pregnant or breastfeeding, you cannot take part in this study. A pregnancy test is required and will be given before you start the study, and before EACH laboratory session. You are responsible for using an effective birth control method such as birth control pills, barrier method (such as condoms or diaphragms), intrauterine device (IUD), hormone implants or surgical sterility while you are taking part in this study. Once you have completed the last laboratory session, you may discontinue birth control immediately. If you become pregnant, you must notify the study doctor immediately.

What if there is new information that may affect your decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent again continue participating in this study.

Will you receive your results from the study?

We may learn things about you from this study which could be important to your health or treatment. If this happens, you can decide whether you want this information to be shared with you. Such information may be that you did not respond well to MT or SMT, or that you express thoughts of suicide. If you decide that you want this information, you may need to meet with experts to help you learn more about your study results. The study will not cover the costs of any follow-up actions. Please initial one of the following options:

_____ Yes, I want my study information shared with me.
(Initials)

_____ No, I do NOT want my study information shared with me.
(Initials)

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions
- The study is cancelled for any other administrative reason

What are the benefits of participating in this study?

There are a number of benefits to participation in this study. Regardless of which treatment you receive, you will have the opportunity to learn a great deal about different techniques to better adjust to your pain, and will learn about chronic pain conditions. Thus, you may gain new skills and knowledge regarding chronic pain and how to manage it.

It is hoped that knowledge gained from this study may help others with chronic low back pain in the future.

What other choices do you have to participating in this study?

The only alternative to participating in this study is not to participate.

Will your information be used for research in the future?

Information or specimens collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, you will not be asked for additional consent.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. John Burns, his study team, and other Rush personnel involved with the conduct and review of this study (which many include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Burns and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Information already in your medical record;
- Information created or collected during the study.

Dr. Burns and his study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- The study Sponsor, The National Institutes of Health, and its representatives;

- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Burns is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Burns at john_burns@rush.edu. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. Data will be coded on paper and transferred to a computer database for later analysis. All paper and computer records and digital audio- ad video-recordings of sessions will be identified only by an ID number rather than your name to help insure confidentiality. All of your records will be maintained in filing cabinets in the locked offices of the study investigators or assistants, and will be accessible only to them. Hard copies of the data will be maintained for 6 years after the study (including the audio- and video-recordings), after which they will be destroyed. Computer data files (with IDs but not your name) will be kept by the study investigators for future use. Your Consent Forms will be kept in a separate locked file separate from the files that contain your data. Your identity will not be revealed on any report, publication, or at scientific meetings. If the results of this study are published or presented in public, information that identifies you will not be used.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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

What are the costs to participate in this study?

There are no costs to you for participating in this research. All costs for the required study visits, examinations, laboratory procedures and naloxone will be paid by the NIH.

Will you be paid for your participation in this study?

You will be paid $605via check for completing the entire study. If you do not finish the study, you will be paid for the study visits you have completed. You will be paid within approximately 4-6 weeks. You will be paid by mail. We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to pay you and for tax reporting purposes to the United States Internal Revenue Services (IRS).

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Burns at 312-942-0379.

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

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

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

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call John Burns, PhD, Professor at 312-942-0379 or email him at john_burns@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?

Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?

Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.
If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Burns in writing at the address on the first page. Dr. Burns may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.

_____	_____	_____
Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

_____	_____
Signature of the Individual Obtaining Consent	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

_____	_____
Signature of the Principal Investigator	Date of Signature