# UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
# CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**Study Title: Mind your Pain: Validating the Mindful Interoceptive Exposure Task (MIET) for patients with chronic low back pain**

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This is a research study about investigating a new phone-based task that may help in managing chronic low back pain. The study researchers, Wolf Mehling, MD and Veronica Goldman from the UCSF Osher Center for Integrative Medicine, will explain this study to you.

**Introduction:** We are asking you to consider taking part in a research study being done by Wolf Mehling, MD and colleagues at the University of California (UCSF) Osher Center for Integrative Medicine, and Irina Strigo, PhD and colleagues at the San Francisco VA Medical Center, the VA Advanced Imaging Research Center (VAARC).

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

**Purpose of the study:** The purpose of this study is to find out more about pain processing and pain management in individuals with chronic low back pain. We are using a variety of pain testing techniques including brain imaging and involves a series of clinical assessments, procedures to determine your sensitivity to different temperatures, MRI, and daily smart phone texting. You have been asked to participate because you have chronic low back pain.

**Study Procedures:** If you choose to be in this study, you will first undergo an eligibility assessment. If eligible, you may then answer a series of questionnaires by mail or online and undergo MRI brain imaging and a series of pain sensitivity tests at the Veterans Affairs Medical Center. These procedures take approximately 2 to 4 hours and will be repeated after 8 weeks (4 to 8 hours). You may choose to complete all or some of the different procedures during each visit.

During these 8 weeks you will receive messages and may answer pain-related questions on your smart phone up to 5 times per day. These phone-based questions will take about 1 minute to respond to each time (2 ½ hours total). The purpose of these questions is to train you in a new form of attention towards your pain sensations. It is a training that may only require to regularly use this phone application. The questions will appear as a message on your smart phone at two times of your preference in the morning and evening. In addition, you are asked to respond to the same questions up to 3 times during the day when you perceive your pain as its worst. There will be two 1-hour training sessions by Zoom video call about how to use the phone task and six additional weekly ~½ hour phone conversations (5 hours).

A detailed Zoom video call interview will take 2 hours and complete the assessments. Therefore, if you complete all procedures, we expect your time commitment to be approximately 10 to 19 hours over 8 weeks.

You will be in this study for 8-10 weeks total and visit the research site at the San Francisco Veterans Affairs Medical Center 2 times. All other activities are online or by Zoom video-call.

**Possible Risks:** There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- General distress, i.e. fatigue, restlessness, anxiety
- MRI related: claustrophobia, muscle aches, fatigue
- Pain sensitivity testing: mild pain, skin irritation.

There are no serious risks of participation.

We will tell you more about these risks and other risks of taking part in the study later in this consent form. There may also be risks that we do not know about.

**Possible Benefits**: There is no direct benefit to you from participating in this study.

**Your Other Options:** You do not have to participate in this study. Your other choices may include:

- Taking part in another study.
- Not taking part in this study

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference. For the part of the study conducted at the VA, we have a separate consent form.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have chronic low back pain.

**Why is this study being done?**
Wolf Mehling, MD, Irina Strigo, Ph.D. and colleagues are conducting a research study to find out whether and how attention and attitudes affect pain sensitivity and brain function. You have been asked to participate because you have chronic low back pain. This study will be performed at the University of California San Francisco and the San Francisco VA Medical Center and VA Advanced Imaging Research Center (VAARC). This study is being funded by the National Institutes of Health.

**How many people will take part in this study?**
About 30 people will take part in this study.

**What will happen if I take part in this research study?**
If you agree and chose to enroll in this study, the following procedures will occur:

- **Questionnaires:** You will be provided a set of questionnaires to fill out. These questionnaires will ask you a variety of questions about topics such as your physical and psychological health, substance use, your thoughts and feelings, etc.
- **Sensory Function Testing:** You will be asked to undergo common procedures(s) that measure your sensitivity to thermal stimulations. This will occur by using a device called a thermode (which will emit different temperatures), by submerging your hand into a water bath, or using a device called a thermal grill. (More details are described in the VA consent form)

All of the stimulations you will receive as part of the sensory tests range from non-painful to moderately painful, with temperatures being a) both hot and/or cold (32-127.4 degrees Fahrenheit) and b) applied to your skin for short periods of time: less than 90 seconds. You will be asked to rate the sensations you experience using a scale. Additionally, you may be asked to perform simple cognitive tasks or view images while receiving these stimulations. When undergo an MRI, your ratings of the sensations may determine the temperatures you will experience from the thermode during other procedures you may choose to complete.

This part of the visit will last approximately 1-2 hours.

**None of the temperatures during the sensory tests will damage your skin or subcutaneous tissue.** You may experience temporary redness of the skin that will go away later. During this procedure, we may use monitoring devices to observe and record basic physiological information (e.g. breathing, pulse, heart rate, etc.)

If you find the sensory testing uncomfortable or painful and would like to discontinue, you can let our staff know at any time and we will end the procedure.

**Magnetic Resonance Imaging (MRI):** An MRI is an electronic picture of your brain created using a strong magnet instead of x-ray energy. You will be asked questions about MRI safety during screening and again at the time of the MRI by staff at the clinic. The MRI scan will be performed at the VA Advanced Imaging Research Center (VAARC) at the San Francisco VA Medical Center. **Pregnancy Assessment (females only):** If you are a female and capable of child-bearing, you will be asked a number of questions regarding your use of reliable contraceptive methods (e.g. abstinence, diaphragm, condom, or intrauterine device) in order to be as sure as possible that you are not pregnant.

Exclusions from MRI*:* People with pacemakers, aneurysm clips, cochlear implants, or certain other metal/foreign objects in the body are not permitted to do MRI studies. There are no known biological risks from MRI. Even though there are no known risks to an unborn child associated with MRI, women of childbearing potential who are not using reliable contraceptive methods (i.e., a medical device or medication designed and taken to reduce the chance of pregnancy) will be excluded from this study.

MRI Procedure: A picture of your brain and spine will be obtained while basic physiological information (e.g. breathing and heart rate) may be recorded. (More details are described in the VA consent form). This part of the visit will last approximately 1-2 hours.

If there are any potentially abnormal results from the MRI scan requiring additional medical attention, the study team will consult a radiologist. If the radiologist confirms the concerns, the study team will notify your physician directly for them to follow up with you.

If you are or become uncomfortable with any of the procedures being conducted at any time, please let our study staff know and they will stop the procedure. If you have a strong negative reaction to any of the procedures mentioned above, or if you are having thoughts of suicide, then you will not be included in this study and will be promptly referred for psychiatric treatment.

You will undergo these assessments (questionnaires; sensory testing, MRI) two times, at the beginning and again after 8 weeks.

**Are any of these procedures experimental?**
The techniques involved in this study are not experimental, but the goal of the study is understanding pain and is not related to your clinical care. All procedures are performed for research purposes.

- **The Mind-your-Pain task:** In the 8 weeks between the 2 assessments at the SFVAMC lab, you will practice the Mind-your-Pain attention task. This task is new and is based on using your smart phone. It has been used in Australia in 2 studies but never in the US. First you will have an introductory 1-hour session over video call with Dr. Mehling or his research staff at the UCSF Osher Center for Integrative Medicine. He/she will explain the task to you, and how different ways of attention to your low back

pain may affect pain perception.

The task is a one-minute attention task that will lead you through a few questions you will respond to on the phone. This task will be timed and asked by SMS, according to your preferred hour in the morning and near bed time. During the day, you are asked to do the task up to 3 times on your own whenever your pain is the most bothersome. This task will take about 1 minute up to 5 times every day for the entire 8 weeks.

You will schedule to receive a phone call once per week to discuss any questions and difficulties with the task. After the first 2 weeks, you will have another 1-hour video phone conference with Dr. Mehling or his research staff.

- **In-detail exit interview:** The researcher may interview you with a 2 hours long Zoom video call. The researcher will ask you to describe your personal experiences with the attention task and your low back pain. The researcher will make a sound recording of your conversation. After the interview, someone will type into a computer a transcription of what's on the tape and will remove any mention of names. The sound recordings will be obtained by UCSF personnel at the Osher Center for research purpose only and used for transcription and subsequent analysis by the research team. The sound recordings will not be listened to by anybody outside the UCSF research team. The sound recording will then be destroyed.

- **Study locations:** All procedures will be done by phone call or video conferencing with you being in your home and at the San Francisco VA Medical Center. Phone or video conferences will not be recorded except the exit interviews.

**How long will I be in the study?**
Participation in the study will take a total of about 10 to 19 hours over a period of 8-10 weeks, depending on the scheduling and length of the weekly phone calls and the exit interview.

**Can I stop being in the study?**
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.
Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

**What side effects or risks can I expect from being in the study?**
- **Questionnaires:** The questionnaires may be distressing to some participants, and you may experience restlessness, anxiety, or fatigue when filling out questionnaires. You are free to decline to answer any questions or to stop the questionnaires at any time. The study staff will be available to immediately assist with any problems that arise in the interview and will make a referral, if required. However, it is very likely that these feelings of upset or distress will be temporary.

- **Sensory Function Testing:** The sensory testing will cause some pain and/or discomfort and/or temporarily reddening of the skin. However, with the proposed stimulus parameters these stimuli will not damage the skin or subcutaneous tissue. You are allowed and instructed to end participation if your perceived pain from thermal procedures is too great to tolerate.

- **MRI:** If at any time you experience distress or discomfort you may stop the study by pressing a button that will immediately notify the study staff you would like to exit the scanner.
  a. Before the scan, the research team will determine if you are appropriate for the MRI based on the absence of the following conditions: cardiac pacemaker, metal fragments in eye, skin, body; heart valve replacement, brain clips, venous umbrella, being a sheet-metal worker or welder, aneurysm surgery, intracranial bypass, renal, aortic clips; prosthetic devices such as middle ear, eye, joint, or penile implants, joint replacements; hearing aid, neurostimulator, insulin pump; I.U.D; being pregnant or trying to become pregnant; shunts/stents; metal mesh/coil implants; metal plate/pin/screws/wires, or

any other metal implants; permanent eyeliner, eyebrows, and some tattoos.
b. Tasks completed in the scanner may be emotional in nature. For this reason, practice version of all tasks will be completed before the scan, and you may terminate the scan if you become overly emotionally affected.
c. Some people undergoing this procedure become anxious because of the closed space. If this happens to you, you can stop this procedure at any time.
d. Muscular aches from lying on your back for a total amount of up to 2 hours in the scanner.
e. Banging noises that the machine makes while taking pictures. You will be asked to wear ear plugs and headphones in order to minimize the risks of these loud noises to your hearing.
f. Potential muscle twitches or tingling during the magnetic resonance imaging procedure.
g. As the risks of scanning during pregnancy is unknown, if you cannot confirm that you are not pregnant then – for your safety – we will not continue with the study.

- **The Mind-your-Pain task:** It is possible that you will become more aware of your pain. However, this task will not aggravate your chronic pain condition.

For more information about risks and side effects, ask one of the researchers.

**Will information about me be kept private?**
We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:
- Representatives of the National Institutes of Health
- Representatives of the University of California
- Representatives of the Department of Veterans Affairs

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible.

**How will my information be used?**
Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

**Use of your data for other research and data expiration:**
A required part of this research is to save your data in a secure repository/bank for other research studies in the future. This data will not expire. If you do not agree to allow this use of your data for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

**Unknown Risks:**
Because this is an investigational study there may be some unknown risks that are currently unforeseeable. You will be informed if the researchers learn of any change in the amount of risk to you.

**Are there benefits to taking part in the study?**
There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand the relationship between physical and mental health conditions.

**What other choices do I have if I do not take part in this study?**
You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

**Can I stop being in the study?**
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

The study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

**What happens if I want to withdraw from the study?**
If you decide that you no longer wish to participate in this study, please call the research staff at 209-507-4799

**Will information learned from this study be shared with me?**
While you are a participant in this study you will be told if any important new information is found that may affect your wanting to continue. Your participation in this study may also be stopped if the investigator decides that stopping is in your best interest.

If the results of this research might influence your medical care after you have completed your participation, the investigators will contact you to let you know these results.

**What if I am injured as a result of this study?**
It is important that you tell the study investigators, Dr. Wolf Mehling and Dr. Irina Strigo, if you feel that you have been injured because of taking part in this study. You can tell Dr. Mehling and Dr. Strigo in person or call them at 415-353-9506.

**Treatment and Compensation for Injury:**
If you are experiencing a medical emergency, please call 9-1-1. If you incur an injury or illness as a result of being in this study, the University of California San Francisco will ensure that treatment is made available at a UCSF medical facility. If you were following study instructions, the costs of such treatment will be covered by UCSF or the study sponsor (if applicable). If you were NOT following study instructions, the costs of such treatment may be covered by UCSF or the study sponsor (if applicable) or may be billed to your insurer just like any other medical costs, depending on a number of factors. UCSF and the study sponsor do not normally provide any other form of compensation for injury or illness. For further information about this, call the study team at the number(s) provided. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

**Are there any costs to me for taking part in this study?**
No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

**Will I be paid for taking part in this study?**
In return for your time, effort and travel expenses, you will be paid $100 per visit, plus $15 travel reimbursement, in the form of a check or a gift card. You will receive 50 cents for each smart phone response on the attention task (up to $140 over 8 weeks). If you take part in the exit interview you will be paid $100. The total payment amount will be up to $440 plus up to $45 for travel expenses. This is the total amount and includes the amount for the study activities at the VA.

**Contact for future research within our laboratory:**
You are asked if you are interested in getting information about additional research studies within our laboratory. If you are interested, we will contact you with information about these studies and you can decide whether or not to participate in them. These additional studies are separate from this study and your decision

about them will not affect your ability to continue to participate in this study. If at any time you inform us that you are no longer interested in these opportunities, you will receive no further contact regarding related studies.

*Please put your initials in the "YES" or "NO" box to indicate your answer.*

*I choose to be contacted for additional research studies within the VA Pain laboratory:* **yes** ☐ **no** ☐

**What are my rights if I take part in this study?**

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institutions the way you usually do.

**Who can answer my questions about the study?**

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researchers Veronica Goldman at 415-353-9686 *or* Emily Murphy at 415-221-4810 ext. 23324.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

## CONSENT

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____

Date Participant's Signature for Consent

_____ _____

Date Person Obtaining Consent