UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form, which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Neuroimaging Age-Related versus Pain-Related Changes in Pain Modulation
(**N**euromodulatory **E**xamination of **P**ain and Mobility **A**cross the **L**ifespan – **NEPAL** Study)

3. Who do you call if you have questions about this research study?

Principal Investigator: Yenisel Cruz-Almeida, MSPH, PhD at (352) 294-5845

Research Staff: (352) 294-8582

4. Who is paying for this research study?

The sponsor of this study is the Department of Aging and Geriatric Research, the University of Florida Clinical Translational Science Institute (CTSI) and the National Institute on Aging.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this research study is to learn more about how chronic musculoskeletal pain in older individuals (i.e., knee pain) changes the brain and impacts a person's ability to walk and move around. Pain is influenced by biology (like hormones), psychology (thoughts and feelings), and habits (like sleep) that may make older adults more likely to have higher or lower levels of pain. Your expected length of participation consists of four separate visits. You may be asked to return for an additional visit if all procedures are not completed. We anticipate that all visits will be completed within about three weeks.

b) What is involved with your participation, and what are the procedures to be followed in the research?

Your participation involves four separate visits, which are each approximately 2.5 hours long. During your first visit, we will determine your eligibility for the study and will complete a variety of procedures including questionnaires about your mood, thinking and memory tests. If you are eligible, you will proceed with the following visits. The second visit will include magnetic resonance imaging (MRI) scans. During this procedure, we will ask you to perform certain tasks. In another visit, we will perform quantitative sensory testing (QST), that will include touch, vibration, and heat/cold temperature on the hands and feet that assesses your ability to feel sensations. Lastly, in the physical and cognitive performance visit, we will perform tests that assess physical ability such as walking, balance, and strength in the muscles. In addition, some cognitive tests will be completed in this last visit. Given there are 4 study visits, you will be allowed to complete any of the assessments during extra visits if it is most convenient.

c) What are the likely risks and discomforts to you?

Likely risks and discomforts associated with this study include a risk of falling or losing your balance while performing the physical performance procedures and activity tests. The hot and cold pain testing procedures may also produce discomfort at the area of stimulation, which may result in mild reddening of the

skin. There is a slight chance that the pressure testing may leave a small bruise at the area of stimulation. In addition, the MRI may feel uncomfortable if you do not like to be in close spaces. The MRI scanner produces a loud hammering noise, however, earplugs will be given to reduce any risk. Also, the risks of drawing blood from a vein includes discomfort at the site of puncture, which can leave a bruise or swelling at the puncture site. Last, you may feel uncomfortable answering some of the questions on the questionnaires or become stressed or frustrated on the thinking and memory tests.

d) What are the likely benefits to you or others from the research?

There is no direct benefit to you for participating in this research study. However, others could benefit through the researchers gaining a better understanding of the mechanisms of pain that may lead to better treatments for persons with chronic or acute pain.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

There is no treatment associated with this research study, so the alternative to participating is to not participate.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

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 CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Dr. Cruz-Almeida does not provide clinical care. Your clinical care will not be affected by your participation in the current study.

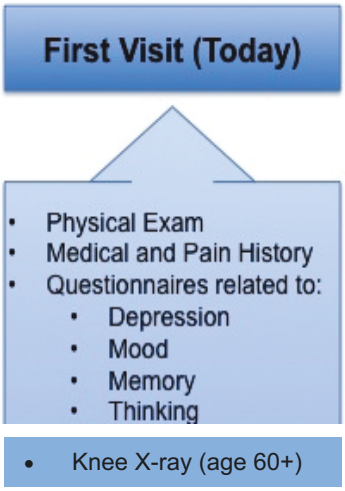
7. What will be done only because you are in this research study?

Tests described below will be done for research purposes only and will not be evaluated or used to diagnose or treat any of your medical problems. These tests may need to be repeated if required for your medical care in the future. If an apparent abnormality is discovered during any of the tests that are performed during the research study, (e.g. results of MRI scans, measurement of blood pressure,

measures of mood and anxiety etc.) you will be informed about it by the research team. You will be provided with a copy of abnormal test results and we will encourage you to see your primary care physician and discuss findings with him/her.

During your first visit to our lab, we will ask you to review this form. The study team member will go over the form and the study with you. You can ask as many questions as you like about the study and this consent form. If you agree to participate in the study after reviewing this informed consent, please sign your name at the end of the form. Signing this informed consent form will allow us to determine your eligibility. If you choose to sign this form, and agree to participate, you will be further screened to determine if it is safe for you to participate in this research study and particularly to have an MRI scan.

We need to learn about your current health status



During your first visit to our lab we will determine whether you are eligible for the study. Your vital signs (heart rate, blood pressure), waist circumference, height, and weight will be measured. If you are ineligible for this study because you have health problems that interfere with the study or the study would put you at risk, you will still be compensated for your time and travel expenses you incurred to come to this visit.

We will also measure how well you can feel certain sensations, your thinking and memory, and how well you can follow instructions to make sure the procedures are safe for you.

If it is determined that you are eligible for the study

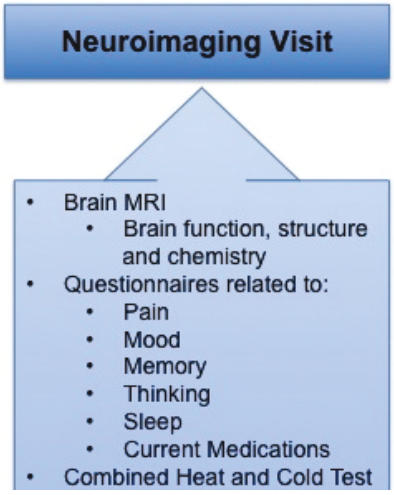
If you agree to the study and it is determined that you are eligible, you will be given additional questionnaires concerning your health, pain, sleep, activity levels, and coping styles. You do not have to answer any questions that you would rather not answer.

If you are of child-bearing age (for example between the ages of 9 and 62), we will administer you a pregnancy test to ensure you are not pregnant as we do not know how our laboratory testing may impact pregnancy. If you are found to be pregnant, you will not be able to participate in our study.

Then, we will ask you to complete several short tests regarding your thinking and memory. For these tests, we will ask you some questions that you will need to remember. We will also ask you to follow some commands, and to write and draw some pictures. **At the end of this session, if you are over 60 years of age, we will also take you to get a knee x-ray.**

You will be scheduled to come for three experimental visits. We would like to complete all study visits within a one-month period, although they may be divided if you would like. We will expect that visits will be scheduled no more than one week apart.

1) Baseline MRI Neuroimaging Visit



We would also like to take pictures of your brain using magnetic resonance imaging (MRI). MRI is a procedure that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. This procedure is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MRI scan in case any problems occur. During the MRI, we will also apply a series of stimuli using either a thermode that produces heat stimulation or a small, plastic, pinprick device, which you may experience to be painful, since we are also interested in examining changes in your brain when you experience pain. The thermode will be placed on one or both forearms. We will also ask you to look at a screen and answer a few questions to examine changes in your brain when you are thinking and concentrating. We will also measure chemical changes in your brain using a technology called magnetic resonance spectroscopy or MRS for short. The neuroimaging may take approximately 2 hours to complete. This time includes your wait time at the MRI center where you will answer some questions about your pain (if any), mood and sleep before laying in the scanner.

If an obvious abnormality is discovered during your MRI scan, you will be informed about it by the research team and we will encourage you to see your primary care physician. During the MRI procedure, you may be asked to rate your pain and to perform some memory/concentration tasks.

Would you like to participate in the neuroimaging part of the study?

_____Yes

_____No

Blood sample: We will collect a small sample of your blood during this study visit after the neuroimaging. A small needle will be inserted into a vein in your arm or hand and we will draw about 4 tablespoons of blood. This will take about 5-10 minutes. The blood will be used to help us understand your response to pain. We will see if you have chemicals in your blood that we think make people more sensitive to pain.

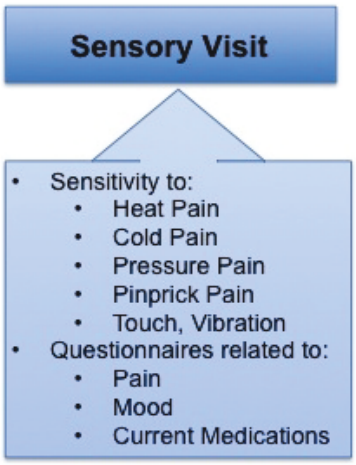
Would you like to participate in the blood draw part of the study?

_____Yes

_____No

Combined Heat and Cold Test: After the neuroimaging and 10 minutes of rest, we will conduct some heat and cold pain testing procedures, where we will test how the heat pain feels by itself, and then we will test how the heat pain feels after you remove your hand from a cold water bath. First, we will have you rate several heat pulses. Then, we will ask you to put your hand into the cold water for up to a minute. After you take your hand out of the cold water, we will ask you to rate the heat pulses one more time. You can stop any of these procedures at any time.

2) Baseline Quantitative Sensory Testing (QST) Visit



All participants will undergo a sensory assessment called Quantitative Sensory Testing or QST that will assess in detail your ability to feel sensations due to touch, vibration, and changes in temperature on your skin at several locations, some pre-selected (i.e., hands and feet) and some unique to you (in an area where you experience chronic musculoskeletal pain, if any).

Touch sense: We will measure your touch sensitivity by applying small, plastic, blunt-tipped sticks (filaments) of differing thickness against your skin. The larger filament is about the thickness of a toothpick and the smaller is about three-quarters that size. We will touch your skin with one filament at a time and ask you to tell us if you feel any painful sensation. If you have pain, we will also assess for the presence of a pain response to touch that is normally not painful by using another plastic filament about one-third the thickness of a toothpick lightly tapping your skin 1 to 10 times. Additionally, we will brush your skin with a soft-bristle paint brush 1 to 10 times.

Vibration sense: We will use a small blunt device that vibrates more and more vigorously over time and you will be asked to let us know when you first start to feel the vibration. We will repeat this procedure 3 times at each test site (hands, feet and painful areas).

Temperature sense: a small metal heating/cooling surface, about the size of two adjacent postage stamps, will be placed on your skin. You will be asked to tell us when you first feel coolness, warmth, or pain due to cold or heat. We will repeat this 3 or 4 times at each site.

- Sensitivity to Heat: One type of sensation; will be produced by a small heat probe or heated metal plate placed on your skin that will increase in temperature. You will feel several different levels of heat. Some of these temperatures might cause you to experience pain and you can stop the

procedure at any point if you desire. You will be asked to tell the researcher how the heat feels to you by rating the sensation using numbers or a sliding scale.

- Sensitivity to Cold: A second type of sensation will be produced by a small cold contact or cold metal plate placed on your skin for very short periods of time. If this will cause you to experience pain and you can stop the procedure at any point if you desire. You will be asked to tell the researcher how the cold feels to you by rating the sensation using numbers or a sliding scale.

Pressure sense: Another type of sensation will be produced by a device that will be pressed against the skin for several seconds. This might produce pressure pain, similar to what you would feel if you pressed your finger against your skin. You will be asked to press a button and give a rating to indicate how the pressure feels to you. You may stop the pressure trials at any time.

Pinprick Pressure: We will also apply a series of weighted pinprick probes. We will ask you to tell us which probes produce pain and then a weighted probe will be applied several times in a row and you will be asked to rate the pain experienced from the probe. In addition, we will apply the same small, plastic, pinprick device used during the neuroimaging visit to your hand and foot and you will be asked to rate the level of pain you experience at each site.

Before and after the sensory testing procedures, several physical measures will be taken.

Blood pressure and heart rate: We will measure your blood pressure and heart rate with a device that attaches to your arm.

Temperature**:** We will measure your temperature of your skin. This will tell us about how stressed you are. We use round flat sensors that are about the size of a coin that are taped to the skin in places such as your arm, leg, or finger. You will not have any sensation where these sensors are attached to your skin.

3) Baseline Physical and Cognitive Performance Visit

You will perform tests that assess your physical and cognitive abilities and you will be asked questions about your physical function. These tests are not conducted in any particular order and will take approximately 2 hours to complete.

- You will be asked to perform multiple walking tests. You will be instructed to walk at your usual pace, and, if necessary, you can rest at any time. During some of the walking tests, you will have skin sensors attached to your body to help us understand your body's walking and stress response.

- You will be asked to complete some thinking and memory tests on an iPad or computer.
- You will be asked to complete questionnaires that address your physical function and also whether you experience pain during your usual daily activities.
- You will perform tests of your physical ability that include:
  1. Standing up from a chair
  2. Balance tests
  3. Muscle strength tests of your arm and leg.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

There is some flexibility on when the following assessments may be conducted and in general, questionnaires and other testing may be collected during any session that is most convenient for you as long as it is collected before you complete the study.

8. How long will you be in this research study?

Your expected length of participation for the baseline data collection is approximately ten hours total, over the course of four separate visits. You may be asked to return for an additional visit if all procedures are not completed. We anticipate that all visits will be completed within about three weeks.

9. How many people are expected to take part in this research study?

We anticipate that we will need to enroll and screen 350 people to achieve the targeted number of participants needed for study completion of 250.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

General pain testing: During the sensory tests sessions you are likely to have unpleasant feelings or feel pain. This is intended because the investigator studies

pain sensation. Individuals who are taking narcotic drugs or illicit drugs might be at a higher risk in this study. They might not feel or respond to pain normally. We strongly discourage such persons from volunteering for this study.

Heat probe: Several things may occur in the area of skin (1 inch square) after the heated probe contacts your skin: (1) It may turn red like a mild sunburn, and (2) there may be a slight burning feeling after the heat is removed. For most people this is gone in 1-2 minutes. It may take up to 1-2 hours for all the symptoms to disappear. It is very unlikely (less than 1% chance) that you will get a burn serious enough to cause a blister. In addition, you can stop any testing at any time if the pain becomes intense. The risk of an electrical injury as a result of your contact with the test equipment is very small and comparable to the electrical shock risk of a common household appliance.

Pressure: There is a slight chance that a small bruise may form as a result of the testing your sensitivity to pressure. If a bruise should appear it is usually short lasting and not painful.

Questionnaires: You may feel uncomfortable about answering some of the questions on the questionnaires. You are free not to answer those questions.

Heart rate, blood flow and skin temperature. During the testing, we may measure several vital signs such as your heart rate, the rate of blood flow or temperature of your skin. We will use round flat sensors that are about the size of a coin that are taped to the skin in places such as your arm, leg, or finger. There may be some discomfort when the tape holding a sensor to your skin is removed. However, the values of these measures will not be readily available to the participant or the experimenter.

Drawing blood: The risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely, an infection; and, uncommonly, faintness from the procedure. We reduce these risks by using sterile needles, alcohol scrub, applying pressure to your arm after we remove the needle, and using a trained technician or nurse experienced in collecting research blood samples.

Physical function tests: There is a risk of losing your balance and falling associated with the physical performance-based testing (e.g., the ¼ mile walk test, balance tests, rising from a chair) and participation in physical activity. Falling also places you at risk for a bone fracture. There is also a risk of injury to muscles or tendons/ligaments. We will minimize this risk by: (1) safely escorting you to chairs located along the walking course should you become unsteady; (2) following you at a close distance; and, (3) being at your side should you need assistance. After the strength tests, you may experience muscle soreness and muscle fatigue.

MRI: The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for example, any pacing device (such as a heart pacer), any metal in your eyes, or certain types of heart valves or brain aneurysm clips. In a separate survey, someone will ask you questions about your eligibility to have an MRI scan. Also, there is not

much room inside the MRI scanner. You may be uncomfortable if you do not like to be in close spaces. During the procedure, you will be able to talk with the MRI staff through a speaker system, and, in the event of an emergency, you can tell them to stop the scan. Finally, the MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs and headphones to reduce this risk.

This research study involves exposure to radiation from a knee x-ray. The radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you will receive in this study is less than 1 mrem, and is approximately equivalent to a uniform whole body exposure of less than 1 day of exposure to natural background radiation. The risk from this radiation exposure is considered to be very low when compared with other everyday risks.

Memory and concentration tests: You may find these tests stressful. You might feel tired or sad because it may be difficult to remember things that you are asked to remember. You may skip any question you do not wish to answer.

Research staff will explain what to do during your clinic visits. There is no right or wrong answer on these tests, and test scores by themselves do not mean that you have a problem with your memory or mental abilities.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally

funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

11a. What are the potential benefits to you for taking part in this research study?

There is no direct benefit to you for participating in this research study.

11b. How could others possibly benefit from this study?

If this research contributes to a better understanding of how pain works, it may lead to better treatments for persons with chronic or acute pain. This would benefit future patients.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

Participation in this study is entirely voluntary. You are free to refuse to be in the study, and your refusal will not influence current or future health care you receive at this institution. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

Data that have been collected up to the time point of your withdrawal may be used. However, no additional data or medical information will be collected or requested.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- You need a medical treatment not allowed in this study.
- The investigator decides that continuing in the study would be harmful to you.
- It is difficult for you to rate the pain intensity during pain tests.
- You are unable to keep appointments.
- If you do not follow the instructions given by the investigator or the study team
- This study is cancelled due to lack of funding or other administrative reasons.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

Study Services

The Sponsor will pay for or provide all study services/activities required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact Dr. Yenisel Cruz-Almeida at 352-273-5971.

Items/Services Not Paid for by the Sponsor

Any other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

15. Will you be paid for taking part in this study?

Yes. You will be compensated in the amount of $35 for each session that you attend, for a total of up to $175.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on

amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

The study team will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to nonresident aliens must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. Yenisel Cruz-Almeida at 352-294-5845 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Your contact information
- Information you provide regarding your health history, medical conditions and treatments.
- List of medications you are taking
- Your responses to study procedures including sensory testing procedures.
- Results of assessment of your physical abilities
- Results of imaging by MRI
- Results of laboratory tests assessing chemical markers related to pain perception
- Information obtained from the questionnaires
- Information related to diagnosis of a mental health condition as provided by you.
- Your social security number for compensation purposes

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To learn about differences in pain sensitivity and determine the factors that influence responses to pain.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States governmental agencies who are responsible for overseeing research, such as the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study in a secure database.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

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SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing Date