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: _____

## GENERAL INFORMATION ABOUT THIS STUDY

**1. Name of Participant ("Study Subject")**

_____

**2. What is the Title of this research study (this "Research Study")?**

Contribution of Pain Catastrophizing to Race Group Differences in Pain and Pain-Related Brain Responses in Older Adults with Knee Osteoarthritis (OA) [Study of Pain Catastrophizing] (SPAC).

**3. Whom do you call if you have questions about this Research Study (the "Study Team")?**

Principal Investigator: Ellen L. Terry, PhD 352-273-6441

**4. Who is paying for this Research Study?**

The sponsors of this study are the National Institute on Aging, UF Center for Advancing Minority Pain & Aging Research (UF CAMPAS), and the National Institute of Neurological Disorders and Stroke.

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

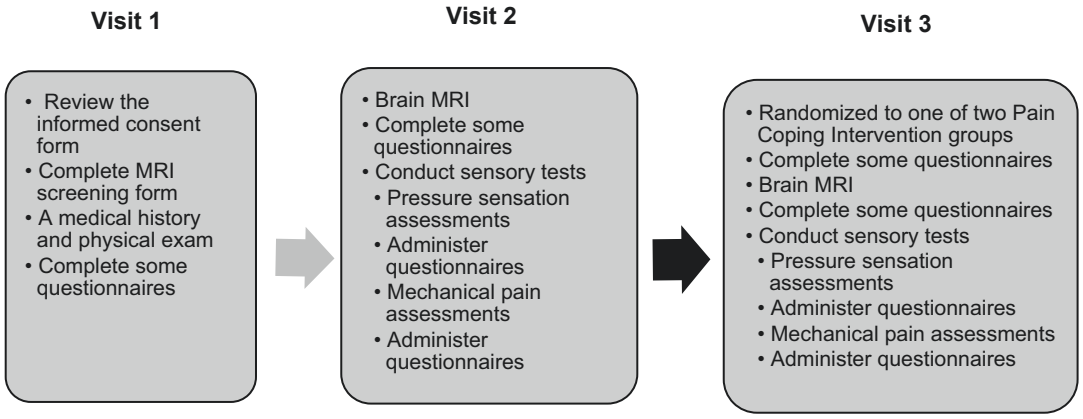
Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions 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 test whether a brief, single session pain coping treatment could influence pain processing in people who have knee osteoarthritis (OA). In this study, we are also looking at your thought and feelings and brain factors that may help the treatment to work better. In addition, people from different ethnic and racial groups may experience OA pain differently, and it is important to find out why this might be the case. Therefore, we are interested in how your racial and ethnic background may affect your experience of OA. Your expected length of participation consists of three visits and we expect that all visits will be complete within one month.

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

Your participation in this study will be over the course of three days. Participation in this study will consist of 3 visits at three separate time points. Each time point will be generally within a week of each visit. Below is what is involve in each visit.




**c) What are the likely risks or discomforts to you?**

- The physical exam procedures and activity tests may produce discomfort
- The MRI may be unsafe if you have metal implanted in your body. The scanner produces a loud hammering noise, however, earplugs will be given to reduce any risk.
- Claustrophobia in the MRI scanner
- The questionnaires may make you feel upset
- Participant will experience pain or discomfort during pain testing

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

There is no direct benefit to you from 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?**

The other option to taking part in this study is not participating.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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.

## 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)?

Regular medical care for your arthritis and other medical conditions will continue to be given by your regular doctors, nurses, and other providers. This study does not offer any medical care.

### 7. What will be done only because you are in this Research Study?

You have already completed a brief telephone or in-person screening to find out if you are eligible for the study. At the first visit, we will collect more health information from you in order to make sure that you are still eligible for the study. In addition, we may ask you to sign a form giving us permission to get medical information from your primary healthcare provider, so that we can make sure it is OK for you to be in the study.

**Procedures for Visit 1**

The following procedures will be done at the first visit:

A. **Informed Consent** a review of the Informed Consent form with you to make sure that you understand everything that is involved in the study

B. **Clinical Medical history and Physical exam**. We will ask you to complete several questionnaires about your physical health including your knowledge on some medical words. Female participants of childbearing potential will complete a one-time pregnancy test at the beginning of the session on day one. In addition, you will complete questionnaires on your thoughts about pain, previous life experiences, and how you think and feel about things. We will ask some personal questions, because this will help us know about all of the things that might be affecting your symptoms of OA. If at this point, we find any health concerns that increase your risks (e.g. high blood pressure) or things that make it unsafe for you to do an MRI (e.g. metal implants) you will not be able

to continue with the study. If you are eligible for the rest of the study, we will ask you to come in for one more visit to our testing center. Also, if you are eligible, we will do the following tests at the first visit.

C. **Questionnaires**. Throughout Visit 1, you will be asked at different times to complete questionnaires about your thoughts and feelings about pain. You do not have to answer any questions that you would rather not answer.

D. This first visit will up to 1.5 hours

## Procedures for Visit 2

The following procedures will be done at the second visit:

A. **Brain MRI**. We will 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 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. This portion will take up to 60 minutes to complete.

B. We will also complete the following pain sensory testing:

- **Pressure Sensations Assessments**. We will use a handheld device with a small (less than ½ inch wide) rubber tip to apply pressure to the knee that hurts you the most, and to your thigh, and shoulder. The pressure will be slowly increased, and you will be asked to tell the examiner when you begin to feel discomfort or mild pain. As soon as you tell us you feel pain, the pressure will be removed.
- **Mechanical Pain Assessments**. We will use a handheld probe that has a small nylon tip to tap your knee and your hand. We will ask you to tell us how painful this feels.

C. This second visit will up to 3 hours.

## Procedures for Visit 3

A. **Pain Coping Intervention**: If you decide to participate in the study and you are eligible, you will be randomly assigned (much like the flip of a coin) to one of the following groups:

1) An intervention group focusing on thoughts in response to pain, and ways in which to manage pain through the development of goal-directed thoughts;

2) An intervention group focusing on learning more about pain processing and knee pain, and ways in which to manage pain through greater knowledge.

B. The next procedures will be identical to the brain imaging and pain sensitivity assessment procedures given on Day 2 which will include completing a series of MRI testing, completing several questionnaires about your health, your thoughts about pain, previous life experiences, and how you think and feel about things, and several different pain sensitivity assessments.

C. Day 3 testing session may last up to 3.5 hours.

**Audio Recording:** We would like permission to audio record any feedback you may have at the end of the study. Audio recording will be conducted at the end of the study in order to obtain feedback on what intervention techniques participants used and whether they noticed any difference during Day 3 testing. These recording will be reviewed by the study team to assess the quality of our treatment visits. These audio recording will not be released and will only be accessible by study investigators. At the end of the study, the recordings will be transcribed and the audio recordings will be destroyed. Do you give permission to have quality control voice recording taken during your last intervention visit?

Initial: _____ Date: _____

Tests done only for research purposes 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.

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 this Research Study, please contact one of the Research Team members listed in question 3 of this form.

**8. What identifiable health information will be collected about you and how will it be used?**

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:

- Medical history
- Mental health history (e.g. depression)
- Physical exam
- Results of laboratory tests
- Results of MRIs, including brain imaging findings
- Responses to questionnaires
- Telephone interviews
- 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.

Because of the nature of the testing, any information and results (e.g., MRIs, questionnaires, clinical examination, pain sensory testing) obtained from your data will not be given to you or your doctor.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

**9. With whom will this health information be shared?**

This health information may be shared with:

- The study sponsor (listed in Question 4 of this form);

- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- 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).

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

### 10. How long will you be in this Research Study?

Your participation in this research project will last about three days and will include three visits total to our testing center at the University of Florida. Visit one will last up to 1.5 hours, visit 2 will last up to 3.0 hours and visit 3 will last up to 3.5 hours. Thus, your total time commitment is expected to be up to 8 hours over a three-day period.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

### 11. How many people are expected to take part in this Research Study?

If you decide to continue to participate in this study, you will be one of approximately 193 people in this research study at the University of Florida at Gainesville.

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

### 12. What are the possible discomforts and risks from taking part in this Research Study?

This study might involve the following risks and discomforts to you:

- The pain testing procedures may be uncomfortable or unpleasant. You will experience some temporary discomfort from the pressure, and mechanical pain testing. However, if you feel the pain is greater than you wish to tolerate, you can stop any of the procedures at any time.
- The physical exam procedures and activity tests may produce discomfort, and you can stop these procedures at any time.

- 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. Someone will ask you questions about this before you have the MRI.
- There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in close spaces ("claustrophobia"). 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. 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 to reduce this risk.

Other possible risks to you may include:

You may feel uncomfortable, upset or sad about answering some of the questions on the questionnaires. You do not have to answer those questions. Researchers will take appropriate steps to protect any information they collect about you. However, if the researcher believes it is in your medical best interest, they may share information with other health care providers so that they can help you. Also, 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 Research Study may also include risks that are unknown at this time.

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.

Researchers will voluntarily disclose, 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.

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

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a 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.

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

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

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.

**13a. What are the potential benefits to you for taking part in this Research Study?**

There is no benefit from taking part in this research study.

**13b. How could others possibly benefit from this Research Study?**

The results of this study may provide information leading to the identification of new coping skills treatments for knee pain.

**13c. How could the Research Team members benefit from this Research Study?**

In general, presenting research results helps the career of a scientist. Therefore, the Dr. Ellen Terry or the co-investigator may benefit if the results of this study are presented at scientific meetings or in scientific journals.

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

Participation in this study is 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.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. You do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

**15a. Can you withdraw from this study?**

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

**15b. Can the Principal Investigator withdraw you from this Research Study?**

You may be withdrawn from this Research Study without your consent for the following reasons:

- If the investigator decides that continuing in the study would be harmful to you
- If you do not meet the study eligibility criteria
- If you do not follow instructions given by the investigator or study team
- If you are unable to keep appointments.
- If the entire study has been stopped

## WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

### 16. If you choose to take part in this Research Study, will it cost you anything?

**Study Services**

The Sponsor will pay for all services 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. Ellen Terry at 352-273-6441.

**Items/Services Not Paid for by the Sponsor**

Any other medical services provided to you that are not directly related to the study will be billed to you or your insurance company. You will be responsible for paying any deductible, co- insurance, and/or co-payments for these services, and any non-covered or out-of-network services.

### 17. Will you be paid for taking part in this Research Study?

You will be paid for your participation in this study as follows:

| Study Activity | Payment |
|---|---|
| Visit 1 | $25 |
| Visit 2 | $40 |
| Visit 3 | $60 |
| **Maximum Payment for Full Compliance** | **$125** |

The total amount you will be paid for completing all study procedures is $125. You will receive partial payment if you do not complete the entire study at $10 per hour.

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.

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.

## 18. What if you are injured while in this Research 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 UF Health 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 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. Ellen Terry if you experience an injury or have questions about any discomforts that you experience while participating in this study

## 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 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing | Date

Signature of Person Consenting and Authorizing Audio Recording | Date