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")?

Carpometacarpal Osteoarthritis: Towards Identification of Biomechanical, Neuromuscular, and Somatosensory Mechanisms

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

Questions should be directed to the Principal Investigator listed below:

Principal Investigator: Jennifer A. Nichols, Ph.D.
Assistant Professor
J. Crayton Pruitt Family Dept. of Biomedical Engineering
352-294-8803 (office)
385-313-0955 (cell)
jnichols@bme.ufl.edu

Other members of the Study Team include:

- Tamara Ordonez (Ph.D. Graduate Student, Biomedical Engineering)
- Thomas Wright, M.D. (Professor, Chief of Hand & Upper Limb Surgery, Orthopaedics)
- Yenisel Cruz-Almeida, MSPH, Ph.D. (Assistant Prof., Dept. Aging & Geriatric Research)

4. Who is paying for this Research Study?

This study is currently funded by the National Institutes of Health through the National Institute on Aging, the University of Florida's College of Medicine through the Clinical & Translational Science Institute, and the Herbert Wertheim College of Engineering through the J. Crayton Pruitt Family Department of Biomedical Engineering.

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 identify how muscle actions, joint movements, and nerve signals contribute to symptoms in thumb osteoarthritis.

You are being invited to participate in either the thumb osteoarthritis subject group, age-matched control subject group, or young-healthy subject group. Individuals in the thumb osteoarthritis subject group have been diagnosed with thumb osteoarthritis. Individuals in the age-matched control subject group and young-healthy do not have hand pain and have not previously had hand surgery.

As a subject in this study, you will participate in 3 testing sessions. Sessions can be scheduled on the same day or different days based on your preference. The total time commitment across all sessions is expected to be 5 to 7 hours.

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

If you choose to participate, you will complete 3 study sessions:

- *Somatosensory Session*: In the first visit, you will complete questionnaires about your mood, physical function, and whether you experience pain in your daily life. We will also perform quantitative sensory testing (QST), which will involve applying touch, vibration, and hot/cold temperatures on your arms and legs to assess your ability to feel sensations. Finally, you will complete an assessment to evaluate your hand function and strength. This session is expected to take less than 2 hours.
- *Biomechanics Session:* In the second visit, you will be asked to perform simple tasks with your hand, like grasping an object. During the tasks, we will ask you whether you experience any pain. We will also record your joint movements and muscle activity. We will measure your joint movement using motion capture. This means we will secure small reflective markers to your

skin with tape and/or Velcro straps; specialized cameras are then used to record the location of these markers as you move. We will measure your muscle activity (i.e., whether your muscles are "on" or "off") using electromyography (EMG). For muscles that are close to the surface of skin, we will use surface electrodes. This means we will place disposable, single-use electrodes on your skin, like stickers. For muscles that are deeper, we will use intramuscular fine wire needle electrodes. This means we will clean your skin with alcohol and a sterile fine wire/needle combination will be inserted into the muscle. The needle will be removed and the wires will remain in the muscle for the duration of the experiment. At the conclusion of the experiment, the fine wire will be removed. Needles will be inserted and removed by researchers trained in the use of intramuscular EMG. This session is expected to take less than 4 hours.

- *Imaging Session*: In the final visit, we will obtain two x-rays of your hand. If you have recently received hand x-rays as part of your clinical care, we may be able to use those x-rays instead of acquiring new x-rays. This session is expected to take less than 1 hour.

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

Your participation in this study may involve some risks and discomforts, as described below. All precautions will be taken to minimize these risks and discomforts.

Questionnaires & Functional Tests. You may feel unconformable answering some of the questions. You also may become stressed and frustrated when completing the assessments of hand function.

Quantitative Sensory Testing (QST). You may experience discomfort at the stimulation site during the somatosensory testing. The hot and cold pain testing procedures may produce discomfort at the area of stimulation, which may result in mild reddening of the skin. There is also a slight chance that the pressure testing may leave a small bruise at the area of stimulation.

Motion Capture & Surface EMG. You may experience discomfort or skin irritation (i.e., redness) when the marker tape and/or surface electrodes are removed. This discomfort is similar to that experienced when removing a band-aid.

Intramuscular EMG. Participation in this study involves some risks related to the insertion of the intramuscular (fine wire needle) electrodes. There may be some discomfort associated with the insertion of the needle. You may feel lightheaded or uneasy, similar to how you feel when receiving a shot at the doctor's office. There is a low risk of the fine wires breaking, internal bleeding, infection, allergic reaction, fainting, and nerve damage. The electrodes will be sterilized, and the insertion site will be cleaned with alcohol prior to insertion. There is a small risk that a wire fragment may break off one of the electrodes and stay in your muscle. This is highly unlikely and rarely causes any difficulty. However, if this occurs, there is a possibility that surgical removal may be required. These risks will be minimized by selectively choosing the insertion sites and having trained

individuals insert the needles and electrodes. You may feel some fatigue in your muscles after the conclusion of the experiment and will most likely experience some soreness in the area around where the electrodes were placed for a day or two following the experiment. We plan to insert up to 9 fine wire electrodes, but if you experience discomfort, you can choose not to proceed with the full amount of electrodes. You are allowed to stop the insertion of electrodes at any time during the experiment.

Radiation Exposure: This research study involves exposure to radiation from the two hand x-rays. These x-rays are being done for the research study and are not considered part of your standard care. The risk from this radiation exposure is considered to be very small. However, radiation exposure may affect an unborn baby. Therefore, all women of childbearing potential must take a pregnancy test prior to receiving x-rays.

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

There are no direct benefits to you for participating in this research study. However, the knowledge gained from this study will benefit society by providing new information regarding the mechanisms underlying thumb osteoarthritis pain and disability. This could lead to better treatments for future patients with this disease.

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.

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.

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)?

Participation in this study will not affect your normal clinical care.

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

The 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 x-rays, 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 to discuss the findings with him/her.

During your first visit to our lab, a member of the Research Team will discuss this 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, you will sign your name at the end of the form. Your signature will give us permission to enroll you in the research study and access your private health information, as described in this form.

If you are of child-bearing age, we will ask you to take a pregnancy test to ensure that you are not pregnant because we do not know how our laboratory testing may impact pregnancy. If you are pregnant, you will not be able to participate in this study.

The research testing will be divided into three sessions. Each session will be scheduled at your convenience. You may complete multiple sessions in one day or each session on a separate day.

We would like to complete all study sessions within a one-month period. We expect that visits will be scheduled no more than one week apart.

Session 1. Somatosensory Testing

During the somatosensory testing session, you will complete (1) questionnaires related to your mood, pain perception, and hand function, (2) an assessment of hand function, and (3) quantitative sensory testing (QST). Each of these is described in detail below:

(1) Questionnaires

All participants will complete a series of questionnaires, including the Graded Chronic Pain Scale (GCPS), pain experience questionnaire, comprehensive pain history, Short Form Health Survey (SF-36), Brief Pain Inventory, PainDetect, PROMIS Anxiety and Depression short forms, Center for Epidemiologic Studies Depression Scale (CED-D), Beck Depressive Inventory (BDI), Perceived Stress Scale (PSS), Montreal Cognitive Assessment (MoCA), Coping Strategies Questionnaire- Revised (CSQ-R), Satisfaction with Life Scale (SWLS), Revised Life Orientation Test (LOT-R), Positive and Negative Affect Scale (PANAS), the Australian Canadian Osteoarthritis Hand Index (AUSCAN), and the Disability of arm, shoulder, hand score (DASH). Together, these assessments will provide insights into your clinical pain experience and hand function. You are not required to answer any questions that make you feel uncomfortable or that you do not want to answer.

(2) Assessment of Hand Function

All participants will perform range of motion tests, strength tests, and the Jebsen Hand Function test. During the range of motion and strength tests you will be instructed to move your hand and/or grasp sensors in specific ways. During the Jebsen Hand

Function test, you will complete seven timed activities (e.g., stacking checkers, turning over cards) to evaluate fine and gross motor function.

(3) Quantitative Sensory Testing (QST)

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 (e.g., hand and feet) and some unique to you (an area where you experience musculoskeletal pain, if any). This testing will use a variety of stimuli to test different sensations.

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.

Temperature sense: We will place a small metal heating/cooling surface, about the size of two adjacent postage stamps, 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 time, if you desire. You will be asked to tell us 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 time, if you desire. You will be asked to tell us 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, 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.

Session 2. Biomechanics Testing

During the biomechanics testing session, you will be asked to complete grasping tasks with your hands, while three types of data are recorded (1) motion capture data, (2) electromyography (EMG) data, and (3) movement-evoked pain data. Each of these is described below:

(1) Motion Capture Data

Motion capture, which is widely used by the animation industry and biomechanics research community, is a method for measuring human movement. Prior to testing, small, reflective markers will be attached to your skin with tape and/or Velcro straps. These markers will be placed on various locations of your body, including your hand and arm. The position of these markers will be recorded with special infrared cameras as you complete the grasping tasks. Markers will also be placed on some of the objects that you are asked to grasp, so that we can record how the objects move as you grasp them. Some of these objects will also be instrumented with force sensors to record how tightly you grasp them. All participants will complete motion capture.

(2) Electromyography (EMG)

All participants will have their muscle activity (i.e., whether a muscle is “on” or “off”) recorded. Whenever you use a muscle, that muscle produces a small electrical signal, which can be recorded using an EMG electrode. There are two types of EMG electrodes that will be used in this study: surface electrodes and intramuscular (also known as fine wire needle) electrodes. Surface electrodes are approximately the size of a quarter and are attached to the skin, like stickers. Surface electrodes allow us to measure activity from muscles that are located directly underneath the skin. Intramuscular electrodes are very thin wires that are inserted directly into the muscle belly. Intramuscular electrodes allow us to measure activity from muscles that are located deeper in the body.

We will be measuring the activity of arm muscles that are used to stabilize the arm and allow your hand to grasp objects. We may record data from up to 19 muscles in the hand, forearm, upper arm, and shoulder. By measuring muscle activity throughout your arm, we will be able to determine which muscles are used to create certain movements.

During placement of fine wire needle electrodes, we will clean your skin with alcohol and a sterile fine wire/needle combination will be inserted into the muscle. The needle will be removed and the wires will remain in the muscle for the duration of the experiment. At the conclusion of the experiment, the fine wire will be removed. Needles will be inserted and removed by researchers trained in the use of intramuscular EMG. The fine wire needle electrodes will be inserted through the skin. The needle will be removed following insertion and the wire will remain in the muscle for the duration of the experiment. To assist with placing the electrodes, we may use ultrasound imaging to guide the needle insertion. We may also apply a small stimulus to the electrode to test the placement. This stimulus should not be painful, but will create a twitching sensation at the location of the electrode.

We plan to insert up to 9 intramuscular electrodes, but if you experience discomfort, you can choose not to proceed with the full amount of electrodes. You are allowed to stop the placement of electrodes at any time during the experiment. At the conclusion of the biomechanics testing, all electrodes will be removed.

(3) Movement-Evoked Pain

Before, during, and after each task, all participants will be asked to rate their pain on a numeric scale. This information will be recorded. In combination with the motion capture and EMG data, this information will help us understand how individuals change their joint movement and muscle activity in the presence (or absence) of pain.

Session 3. Medical Imaging

All control subjects will receive x-rays of their hand. These x-rays will be taken from two different views, including lateral view and anteriorposterior (Robert's view). A certified technician will acquire the x-rays.

Participants with thumb osteoarthritis will only receive x-rays if the two views required for this study have not already been acquired as part of the participant's standard of care. The x-rays views ordered as part of standard of care can vary based on clinician preference. However, it is likely that one or both views were ordered to diagnose your thumb osteoarthritis. If one (or both) views are acquired, when you sign this form, you are giving us permission to access those x-rays from your medical record. If one (or both) views have not been acquired, they will be acquired as part of this study.

Following Session Completion:

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?

The Research Team will collect the following information:

- Contact Information (i.e., name, e-mail, phone, address)
- Photographic Images and/or Video Recordings (including face)
- Demographic Information (e.g., age, biological sex)
- Anthropomorphic Measurements (i.e., height, weight, limb length)
- Experimental Data (i.e., responses to questionnaires, data from sensory testing procedures, assessments of your physical abilities, motion capture data on how you move, EMG data on your muscle activity)
- X-ray images
- MRN (to access x-ray images, which are stored in medical records)

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 IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

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?

You will participate in 3 testing sessions. Sessions can be scheduled on the same day or different days based on your preference. The total time commitment across all sessions is expected to be 5 to 7 hours.

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?

We expect 30 subjects to complete this study.

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?

Possible discomforts and risks from this study are described below:

Questionnaires & Functional Tests. You may feel unconformable answering some questions. You are free not to answer any question that makes you uncomfortable.

Assessment of Hand Function. You may become stressed and frustrated when completing the assessments of hand function. You may also experience muscle soreness and/or muscle fatigue after the strength tests. This soreness is expected to last no more than a few days.

Quantitative Sensory Testing (QST). You may experience discomfort at the stimulation site during the somatosensory testing. Specific risks associated with different stimuli and/or procedures occurring during the QST are described below:

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.

*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.

*Motion Capture & Surface EMG**.*** You may experience discomfort or skin irritation (i.e., redness) when the marker tape and/or surface electrodes are removed. This discomfort is similar to that experienced when removing a band-aid.

Intramuscular EMG. Participation in this study involves some risks related to the insertion of the intramuscular (fine wire needle) electrodes. There may be some discomfort associated with the insertion of the needle. You may feel lightheaded or uneasy, similar to how you feel when receiving a shot at the doctor's office. There is a low risk of the fine wires breaking, internal bleeding, infection, allergic reaction, fainting, and nerve damage. The electrodes will be sterilized, and the insertion site will be cleaned with alcohol prior to insertion. There is a small risk that a wire fragment may break off one of the electrodes and stay in your muscle. This is highly unlikely and rarely causes any difficulty. However, if this occurs, there is a possibility that surgical removal may be required. These risks will be minimized by selectively choosing the insertion sites and having trained individuals insert the needles and electrodes. You may feel some fatigue in your muscles after the conclusion of the experiment and will most likely experience some soreness in the area around where the electrodes were placed for a day or two following the experiment. We plan to insert up to 9 fine wire electrodes, but if you experience discomfort, you can choose not to proceed with the full amount of electrodes. You are allowed to stop the insertion of electrodes at any time during the experiment.

Radiation Exposure: This research study involves exposure to radiation from the hand x-rays. 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 0.2 mrem, and is approximately equivalent to a uniform whole body exposure of less than 6 hours of exposure to natural background radiation. The risk from this radiation exposure is considered to be very low when compared with other every day risks. However, radiation exposure may negatively affect an unborn baby. Therefore, all women of childbearing potential must take a pregnancy test prior to receiving x-rays.

This Research Study may also 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.

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.

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 are no direct benefits to you for participating in this research study.

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

The knowledge gained from this study will benefit society by providing new information regarding the mechanisms underlying thumb osteoarthritis pain and disability. This could lead to better treatments for individuals with this disease.

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

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at professional meetings or in journals.

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

You may choose not to participate in this study.

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. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

If you are a student, you have been invited to participate in this research project because you have expressed interest in the study. The investigators associated with this project may or may not teach in your college or be associated with courses for which you are enrolled or might be expected to register in the future. Your participation in this study is voluntary and any decision to take part or not to participate will in no way affect your grade or class standing. If you believe that your participation in this study or your decision to withdraw from or to not participate in this study has improperly affected your grade(s), you should discuss this with the dean of your college or you may contact the IRB office.

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 you are not able to complete the research tasks.
- If you are not able to follow the instructions given to you by the Research Team.
- If you are not able to keep appointments.
- If you need medical treatment not allowed in this study.
- If the Research Team decides continuing in the study would be harmful to you.
- This study is cancelled due to lack of funding or other administrative reasons.

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

No. The Sponsor will pay for or provide all study services/activities required as part of your participation in this study. There will be no costs to you for participating in this Research Study. If you receive a bill related to this study, please contact Dr. Jennifer Nichols at 352-294-8803.

If you have recently received x-rays as part of your standard of care, we may be able to use those x-rays for this study. In this case, the x-rays will be billed to you or your insurance company in the usual manner and we will not collect additional x-rays as part of the study.

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.

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

Yes. You will be compensated for each session that you attend, up to a total of $175. As summarized in the table below, the compensation for each session is prorated based on the length of time each session is expected to take.

Study Session	*Expected Time Commitment*	*Compensation*
Somatosensory Session	Less than 2 hours	$50
Biomechanics Session	Less than 4 hours	$100
Imaging Session	Less than 1 hour	$25

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, 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 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 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 Research 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

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Dr. Jennifer A. Nichols, or her successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under her direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. Nichols has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **presentations at scientific meetings outside the University and/or publications in professional journals**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

_____ _____

Signature Date