Cover Page

Project Title: Effect of Knee Pain on Walking Biomechanics

NCT Number: NCT05670236

9/2/2025

SAINT LOUIS UNIVERSITY

Research Study Consent Form

STUDY TITLE:	Effect of knee pain on walking biomechanics

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – your choice.**
- **If you join this study, you can still stop at any time.**
- **No one can promise that a study will help you.**
- **Do not join this study unless all of your questions are answered.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

Please read this consent form carefully.

RESEARCH STUDY CONSENT FORM

Participant:		**IRB #:**	32283
	First Name / Last Name		
Principal Investigator (PI)	Patrick Corrigan, PT, DPT, PhD	**Contact Phone #**	314-977-8541
	First Name / Last Name *Credentials*		
Title of Project:	Effect of knee pain on walking biomechanics		

"You" refers to the person who takes part in the research study.

You are being asked to take part in a research study conducted by Dr. Patrick Corrigan and his research team because you either have knee osteoarthritis or are serving as a healthy comparison.

This consent document may contain words that you do not understand. Please ask Dr. Corrigan or a member of the research team to explain anything that you do not understand.

Key Information for You to Consider

- **Purpose**. The purpose of this research project is to understand how knee pain influences the way you walk.
- **Duration.** If you have knee osteoarthritis, it is expected that you will complete four 1.5-hour visits within a 2-week period. If you are healthy, it is expected that you will complete two 1.5-hour visits within a 1-week period.
- **Study Procedures.** At each visit, you will be asked to fill out surveys/questionnaires, complete a clinical examination, and walk on a treadmill under different types of walking conditions. If you have knee osteoarthritis, at your third and fourth visits your painful knee will be injected with a drug that reduces pain.
- **Risks.** Some of the foreseeable risks of your participation include discomfort during setup for the treadmill walking, slipping or falling during treadmill walking, skin irritation, and lower body soreness or stiffness. If you have knee osteoarthritis, you may experience increased knee pain with walking or discomfort, infection, or nerve damage from the injections.
- **Benefits**. You will not directly benefit from participating in this study. However, your participation is expected to help researchers with designing treatments for knee osteoarthritis in the future.
- **Alternatives**. Participation is voluntary and the only alternative is to not participate.

1. WHY IS THIS RESEARCH STUDY BEING DONE?

Knee osteoarthritis is a common disease that results in pain and disability. Emerging research shows that nearly every person with osteoarthritis in one knee will develop osteoarthritis in their other knee within 10 years. This is concerning because people with osteoarthritis in both knees have worse pain, function, and quality of life. The purpose of the current study is to determine if pain in one knee influences how the other knee is loaded during different types of walking (i.e., varying speeds, gradients, and durations). This project is important because it will help researchers determine if knee pain alters walking in a way that makes osteoarthritis more probable in the other knee. Furthermore, this project is important because it will lay foundational knowledge that is critical for developing new treatments for knee osteoarthritis.

This is a single site study, with researchers recruiting individuals to participate only at Saint Louis University. A total of 60 participants will be enrolled: 30 with osteoarthritis in one knee and 30 without knee osteoarthritis. The participants without knee osteoarthritis will serve as a healthy comparison group.

2. WHAT AM I BEING ASKED TO DO?

Overview for those with knee osteoarthritis: If you decide to take part in this study, you will be asked to complete four 1.5-hour visits where you fill out questionnaires and surveys, complete a clinical examination, and walk on a treadmill for approximately 30 minutes. At the third and fourth visits, you will receive a knee injection prior to walking on the treadmill.

Overview for healthy participants: If you decide to take part in this study, you will be asked to complete two 1.5-hour visits where you fill out questionnaires and surveys, complete a clinical examination, and walk on a treadmill for approximately 30 minutes.

Questionnaires and surveys: Demographics (age, sex, gender, race, ethnicity, and occupation) as well as a general and knee-specific medical history will be collected at the first visit. Medical history will include questions about past orthopedic injuries and any other medical conditions. Knee-specific medical history will include surveys and questionnaires about knee pain, function, quality of life, and treatments. In addition to these, you will also be asked to complete questionnaires about your physical activity and comfort with treadmill walking. The only questionnaires that you will repeat at the other three visits are the ones for assessing your knee pain.

Clinical examination: At each visit, you will be asked to complete a clinical examination.
- Height and body mass will be measured with a stadiometer and digital scale, respectively. A stadiometer is a piece of equipment typically found in a doctor's office for measuring how tall you are.
- Blood pressure will be measured with a blood pressure cuff and stethoscope while you are sitting.
- Pain sensitivity will be assessed for your knees and wrist with mechanical algometry. This will involve a researcher slowly applying pressure with an algometer (i.e., a device that measures pressure) that has a rubber tip on the end. Once you perceive pain, you will report it and the researcher will stop applying pressure. Throughout this assessment you will be sitting with

your knees bent to 90 degrees and your feet flat on the floor. When assessing your wrist, we will have you position your arm on a treatment table.
- Muscles, tendons, ligaments, and cartilage will be visualized with ultrasound imaging. First, gel will be applied to your legs to obtain an image. Researchers will then examine structures around your knee as well as structures that play a role in how your knee functions (e.g., soft tissues of your calf, quadriceps, and hamstrings).

Walking Evaluation:
Speed determination and treadmill familiarization. At the first visit, you will walk on a treadmill prior to performing the experimental walking conditions. The primary purposes of this walk is to determine a speed that is comfortable for level, inclined, and declined walking. The secondary purpose of this walk is to familiarize you with walking on a split-belt treadmill. The speed of the treadmill will be set to 0.8 m/s at the beginning of the walk and modified based on your feedback until a comfortable speed is determined. Familiarization will be complete when you report feeling comfortable and show no outward signs of being uncomfortable.

Setup. For each walking evaluation, 59 motion capture markers (small plastic balls) will be attached to your pelvis, legs, and feet. At the first visit, markers will be placed after the familiarization walk to provide you with a 10- to 15-minute break from walking. For the other three visits, markers will be placed at the beginning of the visit since walking speed and familiarization will carry over from the first visit.

Once all markers are attached, you will be asked to stand as still as possible for up to 30 seconds and perform dynamic hip trials. For the dynamic hip trials, you will be asked to flex, extend, abduct, and circumduct your hip to approximately 20 degrees. After both of these tasks are quality checked with the motion capture system, 26 markers will be removed, leaving 33 markers for tracking motion during the walking.

Intra-articular knee injections. Once the 26 markers are removed, you will either begin the walking on the treadmill (visits 1 and 2) or receive an intraarticular knee injection and then proceed to walking on the treadmill (visits 3 and 4). If you are a healthy participant, you will never receive a knee injection. If you are a participant with knee osteoarthritis, you will receive knee injections at your third and fourth visits.

For the injections, 10 mL of 1% lidocaine hydrochloride will be put into your arthritic knee using a lateral approach. All injections will be sterile and ultrasound-guided to ensure your safety and proper placement of drug within your knee joint. Within 5 minutes of the injection, you will experience numbness and likely significant decreases in pain. Dr. Jamil Neme, a physician in the School of Medicine at Saint Louis University, will perform all knee injections and monitor you for at least 15 minutes.

Walking analysis for those with knee osteoarthritis. At your first and third visits, you will be asked to complete level, inclined, and declined walking at comfortable, fast, and slow speeds. The order of these different types of walking will be randomized. The only difference between the first and third visits is whether or not you received a knee injection before walking. At the first visit you will not receive an injection, while at the third visit you will. Each type of walking will be performed for two minutes then immediately followed by two minutes of rest. For the

inclined and declined walking, the treadmill will be set to 8.3% grade (4.8 degrees). This is the maximum gradient for public and business ramps set by the Americans with Disabilities Act, and is therefore representative of gradients that individuals with knee osteoarthritis are exposed to regularly. For the fast and slow walking, the speed of the treadmill will be increased or decreased 20% of the comfortable walking speed determined during the familiarization walk.

At your second and fourth visits, you will be asked to walk for 30 consecutive minutes. For this walk, you will walk at your comfortable speed and 0% grade. The only difference between the two 30-minute walks is whether or not you received a knee injection before walking. At the second visit you will not receive an injection, while at the fourth visit you will.

Functional Near-Infrared Spectroscopy (fNIRS) application. During the two 30-minute walks a research team member will assist you to place a cap that has sensors to measure activity of brain structures during your assessment. These sensors are similar to the sensors in a smart watch that measure heart rate and other body responses. You will be asked to wear this cap throughout the 30-minute walk.

Pain with walking. If you have knee osteoarthritis, you will be asked to report the severity of your knee pain on a 0-to-10 scale for every 5 minutes of walking.

Perceived exertion with walking. You will be asked to report your perceived level of exertion after each type of walking and for every 5 minutes of walking during the 30 minute walk.

Walking analysis for healthy participants. You will complete the same types of walking that the participants with knee osteoarthritis complete. In other words, at your first visit you will be asked to complete level, inclined, and declined walking at comfortable, fast, and slow speeds, and at your second visit you will be asked to walk for 30 minutes at a comfortable speed.

Perceived exertion with walking. You will be asked to report your perceived level of exertion after each type of walking and for every 5 minutes of walking during the 30 minute walk.

Photos/Videos. For dissemination (e.g., publishing or presenting research findings) and educational (e.g., teaching research methods or discussing research findings in classroom settings) purposes, researchers would like to take photos and/or videos of you completing study tasks and procedures. If you have unique body markings (e.g., tattoos) that are visible or any other characteristics that make you identifiable, photos and videos will not be taken. The photos and videos will not contain any identifying information about you and files will be saved without any personal information, such as your name.

May Dr. Corrigan and his research team take photos and/or videos for dissemination and educational purposes?

Response (circle): Yes No

Signature _____ Initials_____

Identifiers might be removed from your data collected in this research and used for future research studies or distributed to other researchers for future research studies without your additional permission.

May Dr. Corrigan or a member of his research team contact you to invite you to take part in future studies?

Response (circle): Yes No

Signature _____ Initials_____

3. HOW LONG WILL I BE IN THE RESEARCH STUDY?

If you have knee osteoarthritis, it is expected that you will complete four 1.5-hour visits within a 2-week period. Visits will be separated by at least two days.

If you are healthy, it is expected that you will complete two 1.5-hour visits within a 1-week period. Visits will be separated by at least two days.

The total time expected for researchers to complete all research activities is approximately 3 years, this research study is expected to be completed by December 2024.

4. WHAT ARE THE RISKS?

There are certain risks and discomforts that may occur if you take part in this research study. In order from most to least likely, risks and discomforts include:

1. **Soreness and/or stiffness in lower body joints and muscles.** This study involves walking at different speeds, inclines, and durations. Because these different types of walking may be unfamiliar to you, they may cause short-term discomfort in your muscles and joints. This is normal response to exercise. To reduce the likelihood of excessive soreness or stiffness, you will be given breaks between the different types of walking. Additionally, you will have a minimum of 2 days between visits, so the likelihood of continued discomfort is unlikely. However, if you experience soreness/stiffness that is disabling and either lasts longer or is more severe than expected, researchers will help you seek medical attention prior to continuing participation in the study.

2. **Skin irritation when removing motion capture markers (i.e., reflective plastic balls).** This study involves attaching small plastic balls to your body with adhesive. When a visit is complete, the balls will be removed from your skin. This is similar to removing a bandaid from your skin. Irritation is expected if your skin reacts to the adhesive or if you have leg hair. In Dr. Corrigan's experience, very few people experience irritation that lasts longer than a few minutes. If you experience lasting

irritation, researchers will recommend over-the-counter ointments and determine whether it is appropriate for you to continue participating in the study.

3. **Increased knee pain. (This risk is only relevant for those with knee osteoarthritis).** If you have knee pain and osteoarthritis, it is likely that you will experience fluctuating pain throughout the study. This is a typical presentation of knee osteoarthritis, and the study is designed to alter your pain for short periods of time. Researchers will closely monitor your pain throughout the study. If your pain increases to a point where you can no longer walk, testing will be stopped immediately, and you will not perform any remaining physical tests/procedures. Regardless of how bad your pain is, at the end of each visit, researchers will offer you a bag of ice for short-term pain relief.

4. **Loss of privacy during data collection.** The research lab is accessible to faculty, staff, and students within the Department of Physical Therapy and Athletic Training. It is possible that individuals not directly involved in this study will access the lab during your visits. To minimize this risk, signs will be posted outside the lab requesting privacy during testing.

5. **Discomfort or lightheadedness from prolonged standing during preparation phase of motion analysis.** When preparing for treadmill walking, you will be asked to stand for 10-15 minutes while researchers attach small plastic balls to your lower body. While standing, you may experience discomfort or lightheadedness. To minimize this risk, you will be instructed to occasionally bend your knees and shift your body weight. If you become lightheaded, proper medical care will be provided including lying down and monitoring vital signs. If additional medical care is needed, researchers will call for an ambulance.

6. **Local discomfort, infection, and/or nerve damage from injection. (This risk is only relevant for those with knee osteoarthritis).** Like receiving a flu shot, discomfort is expected following the knee injections. We expect the discomfort to be temporary, lasting for only 2-3 minutes. If discomfort continues, the research team will discuss options for reducing injection pain with you and determine appropriateness of continuing your participation in the study. Infection is rare with knee injections. In order to keep the likelihood of infection low, researchers will use sterile (i.e., free from bacteria or other microorganisms) procedures. Nerve damage is also rare, but possible. To reduce the possibility of nerve damage, we will use ultrasound imaging to guide the injection into your knee joint. If signs or symptoms of infection or nerve damage occur, we will help you seek medical attention.

7. **Side effects of the drug used for reducing knee pain (This risk is only relevant for those with knee osteoarthritis).** Researchers will be using a drug called lidocaine hydrochloride to numb your knee joint. Although it is unclear how often side effects occur, it is recommended for you to seek medical attention if you experience any of the following: Bluish-colored lips, fingernails, or palms blurred or double vision; chest pain or discomfort; cold, clammy, or pale skin; confusion; continuing ringing or buzzing or other unexplained noise in the ears; cough; dark urine; difficulty breathing; difficulty swallowing; dizziness or lightheadedness; dizziness, faintness, or lightheadedness

when getting up suddenly from a lying or sitting position; drowsiness; fast heartbeat; fever; headache; hearing loss; hives, itching, skin rash; irregular heartbeat; irregular, fast or slow, or shallow breathing; loss of consciousness; puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue; rapid or slow heart rate; seizures; slow or irregular heartbeat; sore throat; sweating; tightness in the chest; tremor; twitching; unusual bleeding or bruising; unusual tiredness or weakness. There is also the possibility of other side effects. During the study, Dr. Neme will monitor you closely for any side effects for at least 15 minutes after the injection is complete, then Dr. Corrigan will monitor you for the remainder of your visit. If any side effects occur, researchers will help you seek immediate medical advice and attention.

8. **Slipping or falling while walking on the treadmill.** As a part of this study, you will be expected to walk on a treadmill. Because treadmill walking may be unfamiliar to you, researchers will educate you on the use of the treadmill prior to walking. To ensure your comfort, researchers will gradually increase the speed of the treadmill and discuss your comfort level. To ensure your safety, you will be asked to wear a fall-safety harness while walking on the treadmill and remain within arms-reach of the hand rail. If you slip or fall, researchers will stop the treadmill immediately, assess the severity of the slip/fall, and determine if other injuries occurred that require medical attention. First-aid will be provided by researchers as needed. If further immediate attention is needed, researchers will call an ambulance for you. Regardless of the severity, researchers will follow-up with you the following day to ensure appropriate care was received and to determine next steps in study participation.

9. **Loss of confidentiality.** As this study involves the use of your personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening, as described in section 7 of this form.

10. **Discomfort while wearing functional near-infrared spectroscopy (fNIRS) cap.** The fNIRS cap, which will be placed on your head for a portion of study, is designed to be snug and the diodes may exert some pressure on your scalp. Efforts will be made to minimize discomfort by adjusting the pressure of each sensor in the cap. If you have continued discomfort fNIRS will not be completed.

11. **If you are a woman of childbearing potential, please read and sign below.**
Study medications or procedures could cause severe birth defects, mental disability in an unborn baby, or loss of an unborn baby. If you take part in this study, you must be willing to have a pregnancy test done before beginning your participation and you must avoid becoming pregnant while you take part in the research study.

    If you are pregnant or breast feeding a baby, you cannot take part in this research study. If you become pregnant during the study, you will be removed from the study. If you are pregnant or think you are pregnant, it is important for you to tell the study team immediately.

If you are sexually active during your participation, you must use effective measures (chosen in consultation with your health care provider) to avoid becoming pregnant.

Your signature below indicates you understand the risks and agree to the requirements.

☐ Check this box if this section does not apply to you (no signature needed).

Signature _____ Date_____

12. **Adverse reactions to the drug used for reducing knee pain (This risk is only relevant for those with knee osteoarthritis).** Although rare, adverse reactions to lidocaine hydrochloride are possible. The list below is provided by the drug manufacturer and includes adverse reactions, regardless of dosage and form of administration (e.g., inhaled, rubbed on the skin, injected in a joint, injected in the spine). Because lidocaine is widely used in medicine, from pain-relief ointments and patches purchased over-the-counter at drug stores (e.g., Bengay, Aspercreme, IcyHot, Salonpas) to regional anesthesia during medical procedures (e.g., child delivery, orthopedic surgeries, dental procedures), the list below includes a variety of possible adverse reactions. In this study, your risk of these adverse reactions is minimized by: 1) using ultrasound imaging to guide the injection in your knee, 2) having a licensed physician (Dr. Neme) with relevant training and experience perform the injections, and 3) using a dose of 100 mg per injection, which is well below the maximum recommended dose of 3-5 mg per kg of body mass every 90 minutes. For more safety information, please ask Dr. Corrigan or Dr. Neme. The side effects listed above in item #7 are clinical signs of the following adverse reactions.

Systemic. Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption, or inadvertent intravascular injection, or may result from a hypersensitivity, idiosyncrasy, or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

a. Central Nervous System (CNS)
    i. CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestations may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.
    ii. Drowsiness following the administration of lidocaine HCl is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

b. Cardiovascular System
    i. Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.
c. Allergic
    i. Allergic reactions are characterized by cutaneous lesions, urticaria, edema or anaphylactoid reactions. Allergic reactions may occur as a result of sensitivity either to local anesthetic agents or to the methylparaben used as a preservative in the multiple dose vials. Allergic reactions, including anaphylactic reactions, may occur as a result of sensitivity to lidocaine, but are infrequent. If allergic reactions do occur, they should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.
    ii. There have been no reports of cross sensitivity between lidocaine hydrochloride and procainamide or between lidocaine hydrochloride and quinidine.
d. Neurologic
    i. The incidences of adverse reactions associated with the use of local anesthetics may be related to the total dose of local anesthetic administered and are also dependent upon the particular drug used, the route of administration and the physical status of the patient. In a prospective review of 10,440 patients who received lidocaine HCl for spinal anesthesia, the incidences of adverse reactions were reported to be about 3 percent each for positional headaches, hypotension and backache; 2 percent for shivering; and less than 1 percent each for peripheral nerve symptoms, nausea, respiratory inadequacy and double vision. Many of these observations may be related to local anesthetic techniques, with or without a contribution from the local anesthetic.
    ii. In the practice of caudal or lumbar epidural block, occasional unintentional penetration of the subarachnoid space by the catheter may occur. Subsequent adverse effects may depend partially on the amount of drug administered subdurally. These may include spinal block of varying magnitude (including total spinal block), hypotension secondary to spinal block, loss of bladder and bowel control, and loss of perineal sensation and sexual function. Persistent motor, sensory and/or autonomic (sphincter control) deficit of some lower spinal segments with slow recovery (several months) or incomplete recovery have been reported in rare instances when caudal or lumbar epidural block has been attempted. Backache and headache have also been noted following use of these anesthetic procedures.
    iii. There have been reported cases of permanent injury to extraocular muscles requiring surgical repair following retrobulbar administration.
e. Hematologic
    i. Methemoglobinemia.

To the best of the researchers' knowledge, these are the potential risks and discomforts of participating in this study. However, there may be other risks that are unforeseen or unknown to the researchers at this time.

The research team is willing to discuss any questions you might have about these risks and discomforts.

5. ARE THERE BENEFITS TO BEING IN THIS RESEARCH STUDY?

You may not benefit from participating in this research study. Your condition may get better, stay the same, or worsen. Even though you may not directly benefit, people with knee osteoarthritis may benefit in the future because of what the researchers learn from this study.

6. WHAT OTHER OPTIONS ARE THERE?

You may choose not to be in this research study.

7. WILL MY INFORMATION BE KEPT PRIVATE?

The results of the research study may be published and/or presented at scientific conferences, but your name or identity will not be revealed, and your record will remain private. In order to protect your information, Dr. Corrigan and the research team will assign you with a subject identifier (unique code), store your personal information (name, date of birth, phone number, email address, and mail address) separate from study data, and only use secure means for collecting, analyzing, and storing your data. Furthermore, after 3 years, your personal information will be destroyed, leaving only de-identified data, unless you allow Dr. Corrigan and his research team to contact you for future research.

Throughout the study, Research Electronic Data Capture (REDCap) will be used for collecting, managing, and storing your study data. REDCap is a secure web-based tool that is HIPAA compliant and FDA approved. Other than REDCap, raw data files from motion capture and ultrasound imaging will be stored on secure Saint Louis University managed devices with encryption and servers hosted by Saint Louis University's Information Technology Services.

For dissemination and educational purposes, researchers may take photos and videos of you during study tasks and procedures. If you consented above, videos or photos may be taken, but they will not include your face. If you have unique body marking (e.g., tattoos) that are visible, photos and videos will not be taken. All video and photos will be stored without code or screening numbers to maintain your confidentiality and privacy. Additionally, all videos and photos will be stored on secure servers hosted by Saint Louis University.

In addition to Dr. Corrigan and the research team, The Saint Louis University Institutional Review Board (the Board that is responsible for protecting the welfare of persons who take part in research) and other University officials may review your study records. State laws or court orders may also require that information from your research records be released.

As this research study involves ultrasound imaging, the research team could find out information that affects your health during the course of this study. The researchers plan to provide you with all of their findings. If the researchers are concerned about anything, they will ask you to reach out to your doctor for further examination and provide you with the images on a USB flash drive.

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

8. WHAT ARE THE COSTS AND PAYMENTS?

You will not be responsible for any study costs.

In this study, you will be paid $25.00 per visit in the form of an Amazon.com gift card. Thus, if you are a participant with knee osteoarthritis and complete the entire study (i.e., Four 1.5-hour visits), you will receive a total of $100.00. If you are a healthy participant and complete the entire study (i.e., Two 1.5-hour visits), you will receive a total of $50.00. If you do not complete the entire study, you will receive a pro-rated amount of $25.00 per completed visit. Payment will occur as a single Amazon.com gift card at the end of your participation. Depending on your preference, the gift card can either be mailed or emailed. Regardless of the method of payment, you will receive your gift card within 4 weeks of your final visit.
You will also receive a parking voucher at each visit. Parking vouchers will allow you to park in the visitor parking garage adjacent to the Allied Health Professions Building at no cost to you.

9. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you believe that you are injured as a result of your participation in the research study, please contact the research team and/or the Chairperson of the Institutional Review Board as stated in section 10.

You will receive necessary medical treatment in the event that an injury results because of your participation in this research. The University will have the right to determine whether an injury is related to your participation in this study or happened because of your medical condition or other reasons which are not related to this study. If the injury is due to participation in the research, you will not have to pay for the cost of this treatment unless your injury is due to your own failure to follow study instructions. There are no plans for Saint Louis University to pay for the costs of any additional care. You have not waived your legal rights by signing this form. If you have questions, please call the Saint Louis University General Counsel's office at 314-977-5767.

10. WHO CAN I CALL IF I HAVE QUESTIONS?

If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may contact Dr. Patrick Corrigan at 314-977-8541 or patrick.corrigan@health.slu.edu.

If you have questions, concerns, or complaints about your rights as a research participant and would like to talk to someone not on the research team, please contact the Saint Louis University Institutional Review Board (IRB) at 314-977-7744 or irb@slu.edu.

11. WHAT ARE MY RIGHTS AND WHAT ELSE SHOULD I KNOW AS A RESEARCH STUDY VOLUNTEER?

Your participation in this research is voluntary. You may choose not to be a part of this research. There will be no penalty to you if you choose not to take part. You may leave the research study at any time. Researchers will let you know of any new information that may affect whether you want to continue to take part in the research study.

The investigator may ask you to stop participating in this study if:

1) Your knee pain worsens to a point where alternative treatment is medically indicated
2) A side effect or medical condition occurs that places you at risk of further complications
3) You are unable to participate as instructed
4) You are unable to keep scheduled appointments
5) The research study is cancelled by sponsor or regulatory agency.

Saint Louis University is receiving financial support from the Rheumatology Research Foundation and the Academy of Orthopedic Physical Therapy to assist in the conduct of this research study. The amount of payment is enough to cover the research study doctor's and/or institution's expenses to perform the research study.

12. AM I SURE THAT I UNDERSTAND?

I have read this consent document and have been able to ask questions and state any concerns. The research team has responded to my questions and concerns. I believe I understand the research study and the potential benefits and risks that are involved.

Statement of Consent

I give my informed and voluntary consent to take part in this research study. I will be given a copy of this consent document for my records.

_____
Print Name of Participant

_____ _____
Signature of Research Participant Date

SAINT LOUIS UNIVERSITY – INSTITUTIONAL REVIEW BOARD – APPROVAL STAMP

This form is valid only if the IRB's approval stamp is shown below.

IRB #32283
Approved: 11-29-22
Expires: 12-20-23
Changes Approved: 02-21-23
Board #1
Saint Louis University

I certify that I have explained to the above individual the nature and purpose of the research study and the possible benefit and risks associated with participation. I have answered any questions that have been raised and the participant has received a copy of this signed consent document.

Signature of Consenting Research Team Member	**Date**
First Name / Last Name *Credentials*	
Printed Name of Consenting Research Team Member	