Cover Page

Project Title: Effect of Knee Pain on Walking Biomechanics

NCT Number: NCT05670236

9/2/2025

Protocol Title: Effect of knee pain on walking biomechanics
Protocol Status: APPROVED
Date Submitted: 03/05/2024
Approval Period: 03/13/2024-12/20/2024
Important Note: This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.

* * * Amendment * * *

Amendment

Complete this form and with it, submit any affected IRB materials needing revision. Please provide the entire revised documents (not just revised pages). Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects.

The proposed changes associated with this Amendment are related to personnel only (members added or removed from the research team). Subjects do not need to be notified.

You have completed the Amendment form and can now submit the form.

1. **Number of accrued subjects** 31

2. **Status of Study (check one):**
   - X Continuing to accrue study subjects.
   - Closed to accrual. Date closed:

3. **Special populations (mark as applicable):**
   - Children (<18 years of age)
   - Prisoner population targeted or study participant became a prisoner

4. **Summarize the proposed changes to the protocol in lay terms, including the type of change AND what the change involves.**

   If this is a change in PI a new Department Chair review is required. Please upload the signed document in the Attachments section.

   Updating healthy participant criteria.
   Adding new recruitment strategy.

5. **Provide justification/explanation for the proposed changes.**

   Expanding definition of no pain to exclude only those with a meaningful amount of pain to increase recruitment feasibility.
   Adding another recruitment strategy because recruitment efforts have slowed down and want the project to be complete in the award period.

6. **For sponsor amendments, when did the SLU site receive** X **N/A**

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notification of changes?

7. Will currently accrued subjects need to be notified of changes? N

If no, please justify why not.

Both changes only affect recruitment.

If yes, please explain how AND when notification or re-consenting will occur.

8. Does the SLU IRB Protocol need to be modified? Y
9. Are consent documents modified? N

Proceed to the appropriate section(s) of the protocol and make your changes. Also make necessary changes in the Consent Form(s), Assent Form(s), Recruitment Statement, or other attachments, as applicable. Use track changes or highlight (in yellow) changes to documents being revised. Please upload a tracked/highlighted copy of each revised document to be stamped upon IRB approval.

NOTE: Upload a clean copy (changes or highlights removed) of documents in file formats other than Microsoft Word (i.e., the IRB will remove the tracked changes/highlights on uploaded Word documents).

NOTE: Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects.

Sponsored Studies: Remember to update the Sponsor's Protocol version number and date in the Funding section of the protocol (this information will appear on the approval letter).

List of changed sections:

Personnel Information
Subject Population 8(a-g)
Subject Population 8(h-k)
Attachments (16)

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* * * Personnel Information * * *

Study Personnel Roles:
-Principal Investigator: accepts responsibility for study, must sign obligations, can edit protocol and submit to IRB
-Administrative Contact: additional study contact, may or may not also be member of research team, can edit/prepare protocol and submit to IRB
-Key Personnel (Research Team): SLU member of research team, can view protocol (not edit)
-Non-SLU Collaborator: member of research team from another institution or organization outside of SLU, has no access to system, must be provided with PDF of protocol. NOTE: SLUH/SSM employees who collaborate regularly may obtain a guest SLU account if access to system is needed.
-Department Chair: Official Department Chair, may or may not also be a member of research team, can view the protocol (not edit). NOTE: a proxy may be listed if the Chair is the PI.

IMPORTANT NOTE: Human Subjects Protection Training is mandatory for all research team personnel.

Principal Investigator (PI) Mandatory

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PI must be SLU affiliate.

Name of Principal Investigator (Faculty, Staff or Student)	Degree (MD/PhD)	Title
Corrigan, Patrick	DPT, PhD	Assistant Professor

Email	Phone	Fax
pcorrigan@slu.edu	314-977-8541	

Department Name
Physical Therapy

Human Subjects Training Completed? Y
WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.

Research Experience ***?HELP?***

Dr. Corrigan has been performing human subjects research for approximately 12 years. He has led and been involved in numerous projects funded by NIH and foundations. He has contemporary training and experience that spans from project inception to dissemination of findings.

Research Team Member Duties Picklist

1.	X	Recruitment	2.	X	Obtains consent
3.	X	Determine Subject Eligibility for Accrual	4a.	X	Subject Physical Examinations
4b.	X	Follow-up Visits including physical assessments	5.	X	Perform study procedures or Specimen Collection
6a.		Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.		Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	X	Subject Randomization or Registry	8.	X	Collection of Subject Data
9.	X	Report Data (CRFs, e-CRFs, Spreadsheets)	10.	X	Data Analysis
11a.	X	Review Adverse Events	11b.	X	Treat and Classify Adverse Events
12.	X	Other (Please insert explanation below.)			

Dissemination of study findings.

UserID	CourseCompletionDate	Course
pcorrigan	08-23-2021	CITI Biomedical Research Basic Training
pcorrigan	04-07-2022	COI - No further review needed

Administrative Contact

Name of Administrative Contact	Degree	Title
Price, Samantha	PT, DPT	PhD Student
Daradkeh, Sharf	MPT	PhD Student

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Key Personnel (Research Team)

Name of Key Personnel (Research Team)	Degree	Title	Department Name
Neme, Jamil	MD	Assistant Professor	Family and Community Medicine
Salsich, Gretchen	PhD, PT	Professor	Physical Therapy
Hanselman, Abby	BS	Graduate Student	Physical Therapy
Edamala, Aaron	Undergraduate Student	Student	Physical Therapy
Fennell, Kaila	BS	Medical Student	Student Affairs-Medical School
Panjeton, Geoffrey	MD	SLUCare/SSM Faculty	Anesthesiology
Thompson, Megan	Undergraduate Student	Student	Physical Therapy
Moore, Hailey	Undergraduate Student	Student	Physical Therapy
Barnas, Patryk	Undergraduate Student	Student	Physical Therapy
Al-Zoubaidi, Lara	Undergraduate Student	Student	Student Affairs-Medical School
Faber, Allison	BS	Graduate Student	Biomedical Engineering
Samanta, Justin	BS	Medical Student	Student Affairs-Medical School
Monteiro, Swapnil	BS	Student	Physical Therapy
Laigo, Alexander Jo	Undergraduate Student	Student	Physical Therapy
Torres, Marisol	Undergraduate Student	Student	Physical Therapy
Haug, Jonathan	Undergraduate Student	Student	Physical Therapy

Department Chair Mandatory

The official Department Chair should be listed here. If the Department Chair is the PI, a proxy may be listed.

Name of Department Chair
Sebelski, Chris

Degree
DPT, PhD

Title
Associate Professor

Email
csebelsk@slu.edu

Phone
(314) 977-8724

Fax

Department Name
Physical Therapy

Is this individual also a member of the research team? N

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Human Subjects Training Completed?
WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.

Research Experience ***?HELP?***

Research Team Member Duties Picklist

1.	Recruitment	2.	Obtains consent
3.	Determine Subject Eligibility for Accrual	4a.	Subject Physical Examinations
4b.	Follow-up Visits including physical assessments	5.	Perform study procedures or Specimen Collection
6a.	Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.	Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	Subject Randomization or Registry	8.	Collection of Subject Data
9.	Report Data (CRFs, e-CRFs, Spreadsheets)	10.	Data Analysis
11a.	Review Adverse Events	11b.	Treat and Classify Adverse Events
12.	Other (Please insert explanation below.)		

UserID	CourseCompletionDate	Course
csebelsk	08-23-2009	CITI Biomedical Research Basic Training
csebelsk	04-06-2022	COI - No further review needed

Research Team Roles

Name(s), Degree	Department	Experience	Duties
Corrigan, Patrick, DPT, PhD	Physical Therapy	Dr. Corrigan has been performing human subjects research for approximately 12 years. He has led and been involved in numerous projects funded by NIH and foundations. He has contemporary training and experience that spans from project inception to dissemination of findings.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations, Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis, Review Adverse Events, Treat and Classify Adverse Events, Other (Please insert explanation below.) Dissemination of study findings.
Price, Samantha, PT, DPT	Physical Therapy	Dr. Price is a PhD student who has been performing human subjects research for approximately 6 years. She	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical

		has been involved in numerous studies focusing on lower extremity musculoskeletal biomechanics. Her training spans from project inception to dissemination of findings.	Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Disseminating research findings
Daradkeh, Sharf, MPT	Physical Therapy	Sharf Daradkeh is a PhD student who has been performing human subject research for approximately 4 years. He has been involved in many studies focusing on orthopedic injuries, specifically biomechanics and ACL rehab.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis, Other (Please insert explanation below.) Dissemination of results
Neme, Jamil, MD	Family and Community Medicine	Dr. Neme has been involved in research for the past 8 years. He has experience conducting and collaborating on retrospective and prospective studies in pediatric and adult demographics.	Recruitment, Subject Physical Examinations , Perform study procedures or Specimen Collection, Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed), Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices , Collection of Subject Data, Review Adverse Events, Treat and Classify Adverse Events
Al-Zoubaidi, Lara, Undergraduate Student	Student Affairs-Medical School	Lara has been an undergraduate research assistant in Dr. Corrigan's lab since February 2023. Prior to joining the team, she has no research experience.	Recruitment, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Lara's primary role on this study is to assist with data

			is to assist with data collection, processing, and analysis. She may also be asked to assist with recruitment and screening. For all tasks, she will follow standardized laboratory procedures and be supervised by more senior lab members.
Faber, Allison, BS	Biomedical Engineering	Throughout Alli's undergraduate and master's training she has been involved in research.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Dissemination of results
Samanta, Justin, BS	Student Affairs-Medical School	Justin has been a research assistant in Dr. Corrigan's lab since August 2023. Prior to joining the team, he has little research experience. All of Justin's study-related responsibilities will be overseen by Dr. Corrigan or a PhD student. During data collections, Justin will directly assist Dr. Corrigan or a PhD student in performing study procedures. For example, operating computers used to collect motion and force data, handing Dr. Corrigan or a PhD student equipment or supplies, collecting height, weight, and blood pressure measurements. Throughout data collection, Justin may also be asked to write down field notes or values being measured. For data analysis, Justin will follow standard lab procedures for processing motion analysis data as well as ultrasound data. Again, as a member of our	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Justin's primary role on this study is to assist with data collection, processing, and analysis. He may also be asked to assist with recruitment and screening. For all tasks, he will follow standardized laboratory procedures and be supervised by more senior lab members.

		research team, Justin will work closely with other members of the research team and bring items to be addressed to team meetings.	
Monteiro, Swapnil, BS	Physical Therapy	Swapnil has been a research assistant on Dr. Corrigan's team since August 2023. He has no prior research experience. Swapnil's primary role on this study will be calling or emailing individuals who do not qualify for the study. Notifying those who are screened but do not qualify is a courtesy service. Drs. Corrigan and Price will train and supervise Swapnil throughout the study.	Recruitment, Determine Subject Eligibility for Accrual
Laigo, Alexander Jo, Undergraduate Student	Physical Therapy	Alex has been an undergraduate research assistant in Dr. Corrigan's Lab since September 2023. He has no prior research experience. Alex's study-related responsibilities will be overseen by Dr. Corrigan or a PhD student. During data collections, Alex will directly assist Dr. Corrigan or a PhD student in performing study procedures. For example, operating computers used to collect motion and force data, handing Dr. Corrigan or a PhD student equipment or supplies, collecting height, weight, and blood pressure measurements. Throughout data collection, Alex may also be asked to write down field notes or values being measured. For data analysis, Alex will follow standard lab procedures for processing motion analysis data as well as ultrasound data. Again, as a member of our research team, Alex will work closely with other members of the research	Recruitment, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Alex's primary role on this study is to assist with data collection, processing, and analysis. He may also be asked to assist with recruitment and screening. For all tasks, he will follow standardized laboratory procedures and be supervised by more senior lab members.

		team and bring items to be addressed to team meetings.	
Torres, Marisol, Undergraduate Student	Physical Therapy	Marisol has been an undergraduate research assistant in Dr. Corrigan's Lab since September 2023. She has no prior research experience. Marisol's study-related responsibilities will be overseen by Dr. Corrigan or a PhD student. During data collections, Marisol will directly assist Dr. Corrigan or a PhD student in performing study procedures. For example, operating computers used to collect motion and force data, handing Dr. Corrigan or a PhD student equipment or supplies, collecting height, weight, and blood pressure measurements. Throughout data collection, Marisol may also be asked to write down field notes or values being measured. For data analysis, Marisol will follow standard lab procedures for processing motion analysis data as well as ultrasound data. Again, as a member of our research team, Marisol will work closely with other members of the research team and bring items to be addressed to team meetings.	Recruitment, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Data Analysis, Other (Please insert explanation below.) Marisol's primary role on this study is to assist with data collection, processing, and analysis. She may also be asked to assist with recruitment and screening. For all tasks, she will follow standardized laboratory procedures and be supervised by more senior lab members.
Haug, Jonathan, Undergraduate Student	Physical Therapy	Jonathan has been an undergraduate research assistant in Dr. Corrigan's Lab since October 2023. He has no prior research experience. All of Jonathan's study-related responsibilities will be overseen by Dr. Corrigan or a PhD student. During data collections, Jonathan will directly assist Dr. Corrigan or a PhD student in performing study	Recruitment, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Jonathan's primary role on this study is to assist with data collection, processing, and analysis. He may also be asked to

		procedures. For example, operating computers used to collect motion and force data, handing Dr. Corrigan or a PhD student equipment or supplies, collecting height, weight, and blood pressure measurements. Throughout data collection, Jonathan may also be asked to write down field notes or values being measured. For data analysis, Jonathan will follow standard lab procedures for processing motion analysis data as well as ultrasound data. Again, as a member of our research team, Jonathan will work closely with other members of the research team and bring items to be addressed to team meetings.	assist with recruitment and screening. For all tasks, he will follow standardized laboratory procedures and be supervised by more senior lab members.
Salsich, Gretchen, PhD, PT	Physical Therapy	Dr. Salsich has been an active researcher at SLU for the past 20+ years. She has expertise in lower extremity musculoskeletal biomechanics and has rich experiences performing human-subjects research projects at SLU with funding from NIH, foundations, as well as other sources.	Other (Please insert explanation below.) Dr. Salsich serves as a faculty research mentor to Dr. Corrigan for the grants associated with this project.
Hanselman, Abby, BS	Physical Therapy	Abby has been a research assistant in Dr. Corrigan's lab since January 2022. During her undergraduate studies, she completed coursework related to research methods and design.	Recruitment, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Dissemination of results
Edamala, Aaron, Undergraduate Student	Physical Therapy	Aaron has been a research assistant in Dr. Corrigan's lab since August 2022. Prior to joining the team, he had no research experience.	Recruitment, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject

			Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Aaron's primary role on this study is to assist with data collection, processing, and analysis. He may also be asked to assist with recruitment and screening. For all tasks, he will follow standardized laboratory procedures and be supervised by more senior lab members.
Fennell, Kaila, BS	Student Affairs-Medical School	Kaila has been a research assistant in Dr. Corrigan's lab since February 2023. Prior to joining the team, she conducted behavioral research during her undergraduate studies.	Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Dissemination of results
Panjeton, Geoffrey, MD	Anesthesiology	Dr. Panjeton is an anesthesiologist with particular interests in pain. He has been involved in various research projects throughout his medical training. His involvement in the current project represents a new collaboration. During data collections, he will only be involved with performing knee injections. Once data is processed, he will be involved with analysis and dissemination.	Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed), Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices , Data Analysis, Treat and Classify Adverse Events, Other (Please insert explanation below.) Dissemination of research findings.
Thompson, Megan, Undergraduate Student	Physical Therapy	Megan has been an undergraduate research assistant in Dr. Corrigan's lab since August 2022. Prior to joining the lab, she had no research experience.	Recruitment, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Megan's primary role on this study is to assist with data collection, processing, and analysis. She may also be asked to assist with recruitment

			assist with recruitment and screening. For all tasks, she will follow standardized laboratory procedures and be supervised by more senior lab members.
Moore, Hailey, Undergraduate Student	Physical Therapy	Hailey has been an undergraduate research assistant in Dr. Corrigan's lab since January 2023. Prior to joining the lab, she has no research experience.	Recruitment, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Hailey's primary role on this study is to assist with data collection, processing, and analysis. She may also be asked to assist with recruitment and screening. For all tasks, she will follow standardized laboratory procedures and be supervised by more senior lab members.
Barnas, Patryk, Undergraduate Student	Physical Therapy	Patryk has been an undergraduate research assistant in Dr. Corrigan's lab since January 2023. Prior to joining the lab, he has no research experience.	Recruitment, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Data Analysis, Other (Please insert explanation below.) Patryk's primary role on this study is to assist with data collection, processing, and analysis. He may also be asked to assist with recruitment and screening. For all tasks, he will follow standardized laboratory procedures and be supervised by more senior lab members.

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* * * Subject Population * * *

Subject Population(s) Checklist

Select All That Apply :

X Adults
Cognitively Impaired Subjects
Employees (specifically targeted)
Fetuses
Minors (under 18)
Neonates
Non English Speaking Subjects
Pregnant Women
Prisoners
Students (specifically targeted)
Terminally Ill Subjects
Wards of the State
Other (any population that is not specified above)

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* * * Study Location * * *

Study Location(s) Checklist

Indicate where the study will be conducted. Select all that apply:

X Saint Louis University, Medical Center Campus
Saint Louis University, Frost Campus
Saint Louis University, Madrid Campus
X Saint Louis University, SLUCare Practice Locations
SSM STL (DePaul Hospital, St. Mary's Health Center, St. Joseph (St. Charles, Wentzville, Lake Saint Louis), St. Clare)
Cardinal Glennon Children's Medical Center
Saint Louis University Hospital (SSM Health- SLU Hospital)
SLU-SSM Cancer Center Research Alliance Sites
Other (In the box below, list any off-campus institutions or locations and describe the activities being conducted there. Please provide letters of cooperation and/or IRB approvals from each location to document support/approval of the study. You may provide such documentation as it becomes available, but you may not begin work at those sites until documentation of support is provided to the IRB.) Please refer to the Guidance for involving non-SLU institutions in human subject research.

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* * * General Checklist * * *

General Checklist

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Select All That Apply :

- Collection of Specimens
- X Data collection via e-mail or the Internet
- Deception/Incomplete Disclosure
- Dietary Supplements, Vitamins, and Other Food Agents
- X FDA Approved Device
- X FDA approved drugs, reagents, other chemicals administered to subjects (even if they are not being studied), or biologic products
- Genetic Testing
- HIV Testing
- Human blood, cells, tissues, or body fluids
- International Research or Research on International Populations
- Investigational drugs, reagents, chemicals, or biologic products
- Investigational Device
- X Investigator Initiated Study *?HELP?*
- Medical Records
- X Photography, Video, or Voice-Recording Subjects
- X Questionnaires and/or tests
- Radioisotopes/radiation-producing machines, even if standard of care
- rDNA/Gene Transfer Therapy
- Registry(ies)
- Specimens to be stored for future research projects (must be in consent form)
- Study of existing data or specimens
- X University Indemnified Study (SLU is responsible for liability coverage) *?HELP?*
- Other (clarify in text box to the right)

Single Use. Provide a brief summary and justification for the Single Use Therapy. Note: This application will refer to research. For Single Use applications it is understood that 'research' will mean 'therapy'.

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* * * Funding * * *

Funding Checklist

NONE

Funding - Grants/Contracts

Funding Type	Funded By
Private Agency/Foundation	628
Private Agency/Foundation	628

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NOTE: Applicable grant application, contract or subcontract, investigator's brochure, and sponsor's protocol (for all industry sponsored clinical trials) must be attached. You will be prompted for these in section #16 (Attachments).

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* * * Expedited Paragraphs * * *

To request an Expedited Review, check the appropriate category(ies) below. Provide justification for your request for Expedited Review.

To qualify for expedited review, research activities must (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories below.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a) Research on drugs for which an investigational new drug application (21 CFR Part 31, 32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b) Research on medical devices for which

(i) An investigational device exemption application (21 CFR Part 812) is not required; or

(ii) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

3. Prospective collection of biological specimens for research purposes by non-invasive means.

EXAMPLES: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

EXAMPLES: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiology; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. [FOR IRB use only]. Continuing review of research previously approved by a convened IRB only when condition (a), (b), or (c) is met.

a) Previously approved research where
   (i) The research is permanently closed to the enrollment of new subjects;
   (ii) All subjects have completed all research-related interventions; and
   (iii) The research remains active only for the long term follow-up of subjects.

b) Previously approved research where no subjects have been enrolled and no additional risks have been identified.

c) Previously approved research where the remaining research activities are limited to data analysis.

9. [FOR IRB use only]. Continuing review or research not conducted under an investigational new drug application or investigational drug exemption where expedited categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

* * * Background, Purpose, Study Procedures * * *

Title

Effect of knee pain on walking biomechanics

Complete Sections 1 - 16. In sections that allow reference to sponsor protocol or grant, clearly state section and page numbers. Any information that is different or specific to the local site should be in the SLU application. Specify N/A as appropriate.

1. Background

Page numbers from a sponsor's protocol/grant may be referenced in 1a and 1b.

a) Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of the study, if applicable. Investigator Initiated studies must cite references in the response provided or attach a bibliography. *?HELP?*

Osteoarthritis (OA) affects one in eight adults and is a leading cause of disability. Knee OA is particularly prevalent and accounts for an ~83% of the total burden of OA. In many cases, knee OA begins as unilateral disease; yet, up to 90% of those with unilateral knee OA develop bilateral knee OA within 10 years. This is concerning because bilateral KOA is associated with greater functional decline, worse pain, lower quality of life, and higher healthcare costs. To this end, a critical need exists to determine why knee OA commonly progresses from a unilateral to a bilateral disease.

Knee pain may hasten the progression from unilateral to bilateral knee OA if it influences knee joint loads during walking. Those with unilateral knee OA seem to unload their arthritic knee while walking. Although unloading the arthritic knee likely relieves pain, it may shift load to the contralateral knee and increase the risk of bilateral knee OA. However, the speculation that unilateral knee pain influences contralateral knee joint loads while walking remains largely unsubstantiated. Because walking is commonly recommended for managing symptoms of knee OA, it is important to evaluate the effects of unilateral knee pain on contralateral knee loads during walking. Moreover, since walking mechanics are constantly changing with speed, gradient, and fatigue, it is critical to capture the effect of pain on loading during different types of

gradient, and fatigue, it is critical to capture the effect of pain on loading during different types of walking.

Specific Aims as well as Significance Sections for both grants can be reviewed for more information.
References can be found in the attached bibliography or the grant proposals.

Please save frequently

b) Describe any animal experimentation and findings leading to the formulation of the study, if there is no supporting human data.

N/A

2. Purpose of the study

a) Provide a brief lay summary of the project in <200 words. The lay summary should be readily understandable to the general public.

Knee osteoarthritis (OA) is a highly prevalent disease that often results in pain and disability. Emerging evidence shows that nearly every person with OA in one knee will develop OA in their other knee within 10 years. This progression is concerning because people with OA 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 loading of the other knee during different types of walking (i.e., varying speeds, gradients, and durations). This project is important because it may lay foundational knowledge that is critical for developing treatments that reduce the likelihood of knee OA progression.

Page numbers from a sponsor's protocol/grant may be referenced in 2b and 2c.

b) List your research objectives (specific aims & hypotheses of the study).

Aim 1. Evaluate the effects of unilateral knee pain on contralateral patellofemoral (PF) and tibiofemoral (TF) compartment loads in those with unilateral symptomatic knee OA during level, inclined, and declined walking at comfortable, fast, and slow speeds.
Hypothesis 1.1. Contralateral PF and TF contact forces will be greater during painful walking compared to nonpainful walking.
Hypothesis 1.2. The effect of knee pain on PF and TF contact forces will be greater for inclined and declined walking compared to level walking.

Aim 2. Determine if the presence of unilateral knee pain affects contralateral PF and TF compartment loads during a prolonged walk in those with unilateral symptomatic knee OA.
Hypothesis 2.1. Cumulative loading of the contralateral PF and TF compartments will be greater
during a painful 30-minute walk compared to a nonpainful 30-minute walk.
Hypothesis 2.2. Variability of PF and TF contact forces will be greater during a painful 30-minute walk compared to a nonpainful 30-minute walk.

Aim 3. Describe mechanical changes for the hips, knees, and ankles during prolonged walking in those with unilateral symptomatic knee OA.
Hypothesis 3.1. Increased in unilateral knee pain will be associated with decreases in (a) knee work on the painful side, and increases in (b) knee work on the non-painful side, (c) ankle work on both sides, and (d) hip work on both sides.

Please save frequently

c) **Describe the study design (e.g., single/double blind, parallel, crossover, control, experimental, observational, etc.). If the study is investigator-initiated, a timeline for individual subject recruitment, follow-up, and analysis for the study is required. Also, indicate if the subjects will be randomized.**

This biomechanical study will use a repeated measures design to evaluate the effects of unilateral knee pain on contralateral knee joint loading during different types of walking. Thirty adults with unilateral symptomatic knee osteoarthritis will complete four, 1.5-hour study visits. The first and third visits will include level, inclined, and declined walking at comfortable, fast, and slow speeds. The second and fourth visits will include a 30-minute walk. There will be at least two days between visits. The only difference between each pair of visits is that one visit will involve walking with unilateral knee pain (painful walking) and the other visit will involve walking without unilateral knee pain (nonpainful walking). Individuals will be recruited based on the presence of unilateral knee pain so the painful walking will be representative of their typical walking. For the visits with nonpainful walking, the third and fourth visits, pain will be alleviated by performing an intraarticular injection with a local anesthetic (lidocaine). All walking will be performed in a three-dimensional motion capture environment on a split-belt treadmill that is instrumented with force plates.

A cohort of 30 healthy controls will complete the different walking conditions at two, 1.5-hour study visits. The healthy control group will not receive intraarticular knee injections. The purpose of this cohort is to better understand how walking mechanics in individuals with unilateral knee osteoarthritis compare to similar individuals without knee osteoarthritis.

d) **If subjects will be given placebo, please justify placebo use. *?HELP?***

N/A

3. Study Procedures

a) N Is this project a multicenter study (i.e., same project is conducted elsewhere by a different investigator) OR does this study involve conduct of research at multiple sites?

Is SLU acting as a coordinating center for other sites OR is the SLU PI a direct recipient of a federal grant for this research? If yes, complete and attach the Supplemental Application for Coordinating Center Activities.

Will the SLU site be participating in all parts/procedures/arms of the study?

If No, explain what SLU will NOT participate in:

Please save frequently

Page numbers from a sponsor's protocol/grant may be referenced in 3b, 3c, and 3d.

b) **Describe all the procedures, from screening through end-of-study, that the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care. Specify which procedures are for research and which are standard of care. Please note: The box below is for text only. If you would like to add**

which are standard of care. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the Attachment section (#16).

Potential participants will fill out a screening form in the REDCap Database designated for screening. This database will be monitored by the research team. If an individual is eligible, a member of the research team will call or email (based on preference reported on screening form) to schedule the participant for their first visit. If ineligible, a member of the research team will call or email the potential participant to notify them that they do not qualify for the study. If follow-up information is needed to determine eligibility, a member of the research team will call the potential participant to discuss and clarify any responses on the screening form.

Overview for those with knee osteoarthritis: Participants will be asked to complete four 1.5-hour visits where they fill out questionnaires and surveys, complete a clinical examination, and walk on a treadmill for approximately 30 minutes. At the third and fourth visits, participants will receive a knee injection prior to walking on the treadmill.

Overview for healthy participants: Participants will be asked to complete two 1.5-hour visits where they 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, participants will also complete questionnaires about their physical activity and comfort with treadmill walking at the first visit. The only questionnaires that will be repeated at the other three visits are the ones for assessing knee pain.

Specific questionnaires included in this study are 1) the Physical Activity and Sedentary Behavior Questionnaire (PASB-Q), 2) the Visual Analog Scale (for pain and treadmill comfort), 3) the Knee Injury and Osteoarthritis Outcome Score (KOOS) 4) PROMIS Scale – Pain Intensity 5) PROMIS Scale – Pain Interference 6) Intermittent and Constant Pain Score (ICOAP) questionnaire. Demographics and medical history questions are not a part of any particular questionnaire or survey.

Clinical examination: At each visit, participants will be asked to complete a clinical examination.
- Height and body mass will be measured with a stadiometer and digital scale, respectively.
- Blood pressure will be measured with a blood pressure cuff and stethoscope with participant in seated position.
- Pain sensitivity will be assessed with mechanical algometry at the knee and wrist. This will involve a researcher slowly applying pressure to the kneecap as well as the wrist with a device that has a rubber tip on the end. Once pain is perceived, participants will report it and the researcher will stop applying pressure. Throughout this assessment participants will be sitting with their knees bent to 90 degrees and feet flat on the floor. When assessing the wrist, participants will have their arm resting on a treatment table.
- Anatomic structures will be examined with ultrasound imaging. First, ultrasound gel will be applied to obtain an image. Researchers will then examine structures around your knee joint as well as structures that play a role in how the knee joint functions (e.g., calf, quadriceps, and hamstrings musculotendinous structures).

Walking Evaluation:
Speed determination and treadmill familiarization. At the first visit, participants will walk on a treadmill prior to performing the experimental walking conditions. The purposes of this walk are to determine a comfortable speed for level, inclined, and declined walking, and to familiarize the participant to walking on a treadmill. The speed of the treadmill will be set to 0.8 m/s at the beginning of the walk and modified based on feedback until a comfortable speed is determined. Familiarization will be completed when the participant feels comfortable and shows no outward

signs of being uncomfortable.

Setup. For each walking evaluation, 59 motion capture markers (small plastic balls) will be attached to the participant's pelvis, legs, and feet. At the first visit, markers will be placed after the familiarization walk to provide 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, participants will be asked to stand as still as possible for up to 30 seconds and perform dynamic hip trials. For dynamic hip trials, participants will be asked to flex, extend, abduct, and circumduct their 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, participants 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 the participant is in the healthy control group, they will never receive a knee injection. If the participant is in the OA group, they will receive a knee injection at their third and fourth visits.

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

Walking analysis for those with knee osteoarthritis. At the first and third visits, participants will be asked to complete level, inclined, and declined walking at comfortable, fast, and slow speeds in a randomized order. The only difference between the first and third visits is that an injection of lidocaine hydrochloride will be received during the third visit before walking. 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 at each of the gradients, the speed will be increased or decreased 20% of the comfortable walking speed determined during the familiarization walk.

In addition to the first and third visits, which involve nine types of walking, participants will walk for 30-minutes continuously at their second and fourth visits. The only difference between the two 30-minute walks is that an injection of lidocaine hydrochloride will be received during the fourth visit before walking. For these walks, participants will walk at their comfortable speed and 0% grade.

During the 30-minute walks individuals will have a functional near-infrared spectroscopy (fNIRS) cap placed on their head to monitor hemodynamic response in the cortex of the brain. fNIRS utilizes light-emitting diodes and receptors to measure blood oxygenation in the cerebral cortex (the outer portion of the brain). This is similar to how a pulse oximeter measures blood oxygenation in a finger. The overall safety of fNIRS is well established as minimal risk with a similar risk profile to conventional electroencephalography (EEG).

Pain with walking. For those with knee osteoarthritis, they will be asked to report the severity of their knee pain on a 0-to-10 scale after each type of walking and for every 5 minutes of walking during the 30 minute walks.

Walking analysis for healthy participants. Participants will complete the same types of walking that the participants with knee osteoarthritis complete. In other words, at the first visit

participants will be asked to complete level, inclined, and declined walking at comfortable, fast, and slow speeds, and at the second visit participants will be asked to walk for 30 consecutive minutes. During the 30 minute walk fNIRS will be used as described for the knee OA cohort.

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

c) **If the proposed study is a clinical trial where a drug, vaccine, device or other treatment is compared to a placebo group or comparison treatment group, what are the guidelines or endpoints by which early decisions regarding efficacy or lack of efficacy can be made? For example, it may be reasonable to stop enrollment on a study when efficacy has already been clearly demonstrated, to avoid unnecessary enrollments of additional subjects. Alternatively, it may be reasonable to stop enrollment when it is clear that efficacy will never be demonstrated, given the statistical power of the study as designed. Describe the guidelines that are in place to assist in making these determinations, if relevant to the proposed study.**

N/A

d) **Describe how data analysis will be performed (statistical tests, methods of evaluating data) and indicate the smallest group/unit for which separate reporting will occur. For studies involving a questionnaire, if data and reliability information are available, please describe or provide references. For full board, unfunded studies describe sample size determination and power analysis. If none, please justify.**

We will use descriptive statistics (e.g., means, medians, standard deviations, interquartile ranges) to describe each measurement, including those related to demographics, pain, structure, and biomechanics (movement and loading). Hypothesis testing will be completed using between and within group comparisons. Effect sizes, 95% confidence intervals, and metrics of significance will be calculated and used for interpretation. The smallest unit that will be reported are group level measures.

Please save frequently

e) **State if deception (including incomplete disclosure of study purpose/procedures) will be used. If so, describe the nature of the deception and provide a rationale for its use. Also, describe debriefing procedures or justify a waiver of the requirement to debrief. NOTE: for studies using deception, an alteration of consent must be justified in the Informed Consent section of the protocol (#13) and the debriefing script/statement must be uploaded in the Attachments section (#16). See IRB Deception Guidelines.**

f) **Is there an accepted standard of care and/or standard practice at SLU for the condition/disease/situation being studied? This information will assist in comparing the risk/benefit ratio of study procedures relevant to usual care that would be received outside of the research context. *?HELP?*** Y

If yes, please describe the standard of care and standard practice at SLU for the condition/disease/situation being studied.

There are numerous treatments for knee osteoarthritis, but none of them are considered the standard of care. Usual care for knee osteoarthritis depends on the healthcare team as well as the stage of disease. In early phases of disease, typical treatments include aerobic exercise,

strengthening, stretching, modalities (e.g., laser therapy, heat/ice, ultrasound, electrical stimulation, vibration), weight loss programs, walking programs, acupuncture, bracing and orthotics, and over-the-counter medications and supplements. In middle phases of disease, these treatments are typically supplemented with prescription medications and injectable therapies (e.g., platelet rich plasma, hyaluronic acid, corticosteriods). In late phases of disease, surgical procedures are strongly considered, such as joint realignment or replacement surgeries.

g) Does this study involve any diagnostic imaging, labwork or genetic testing that could result in clinical discovery (diagnoses, genetic mutations, etc.)? Note that this could include discovery that is expected (related to the research) or incidental (not related to research aims, but possible, like a mass/shadow found in imaging despite not looking for it). Y

If yes, please describe and include whether there are plans to share findings with study participants.

This study involves ultrasound imaging of the knee and anatomic structures around the knee. We expect to see structural changes that are common in individuals with knee osteoarthritis (e.g., joint space narrowing, calcifications, meniscal extrusion), but there is also a possibility for incidental findings. Both expected and incidental findings will be shared with participants. If the sonographer is concerned about any findings on imaging, the research team will ask the participant to reach out to their doctor for further examination and provide the participant with the images on a USB flash drive.

h) Is this study subject to the NIH Genomic Data Sharing Policy? N

The NIH GDS policy applies to all NIH-funded research that generates large-scale human genomic data as well as the use of these data for subsequent research and includes: genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomics, epigenomic and gene expression data, irrespective of NIH funding mechanism. Click here for more specific examples.

* * * Radioisotopes or Radiation Machines * * *

You have not selected the Radioisotopes option in the General Checklist. If you would like to add Radioisotopes information, please select the option to enable this section.

4. Radioisotopes or Radiation Machines

In this section, investigators must enter all radiation usage associated with the protocol.

Important: Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-233", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). In these cases, submission to the RSO/RSC should occur after the IRB staff has drafted the informed consent radiation exposure risk statement, or verified the statement that was drafted by the research team (as noted below*). For more information on how to submit for radiation safety review, see RSC instructions or contact the Radiation Safety Officer at 977-6895.

Officer at 977-6895.

(1) It is the responsibility of the PI to assure the accuracy and completeness of the data submitted in this section, consistent with guidelines provided below. (2) For projects requiring radiation procedures, please refer to this guidance.

a) **If applicable, list and quantify the radiographic diagnostic and therapeutic procedures associated with this protocol by clicking "Add" and adding to Table 1 below. (Includes X-ray, fluoroscopy, CT, radioactive materials, nuclear medicine, PET-CT, radiation oncology, accelerator, Cyber Knife procedures, etc.)**

b) **Total estimated research radiation dose * :**

* Calculate from the table above by adding the Effective Dose Subtotals for all procedures.

*NOTE: Informed Consent Radiation Exposure Risk Statement- The appropriate Informed Consent Radiation Exposure Risk Statement template language must be inserted into the SLU IRB Informed Consent, inclusive of applying the total estimated research radiation dose specified in item b) from the table above, as instructed in the SLU IRB Informed Consent Template. Per IRB Guidelines, the language will either be drafted by the IRB staff or drafted by the research team and then verified by IRB staff prior to submission to the RSC for review. Contact the IRB Office at 977-7744 or irb@slu.edu with any questions.

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* * * Devices * * *

5. Devices

a) Please list in the space below all investigational devices to be used on subjects during this study.

b) Please list in the space below all FDA approved devices to be used on subjects during this study.

FDA Approved Devices

Protocol Title: Effect of knee pain on walking biomechanics

Device Name	Manufacturer	Provide IDE #. Documentation of IDE # required unless imprinted on sponsor protocol (attach in section #16).
LOGIQ E10 Ultrasound System	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC	

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* * * Drugs, Reagents, Chemicals, or Biologic Products * * *

6. Drugs, Reagents, Chemicals, Biologic Products, or Dietary Supplements, Vitamins, and Other Food Agents

Pilot	Phase I	Phase II
Phase III	Phase IV	Not Phased

List placebo if it is considered a drug (contains more than inactive ingredients). For example, normal saline is considered a drug that should be listed, whereas placebo tablets are usually inert ingredients that do not need to be listed.

b) Please list in the space below all investigational drugs, reagents or chemicals to be administered to subjects during this study. Attach all applicable Investigator Brochures in section #16 (Attachments).

c) Please list in the space below all FDA approved drugs, reagents, chemicals to be administered to subjects during this study. Attach all applicable package inserts in section #16 (Attachments).

FDA Approved Drugs, Reagents, Chemicals, Biologic Product

Drug Name	Manufacturer	Source (e.g., Pharmacy, Sponsor, etc.)	Dosage
Lidocaine Hydrochloride	Hospira, Inc.	McKesson Corp.	1%, 10 mg/mL

d) Please list in the space below all dietary supplements, vitamins, minerals, or foods to be administered to subjects during this study.

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* * * Other Levels Of Review * * *

7. Other Levels Of Review

Protocol Title: Effect of knee pain on walking biomechanics

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1. University Radiation Safety

Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-223", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). For information on how to submit for radiation safety review, see RSC <a href=https://www.slu.edu/research/faculty-resources/research-integrity-safety/documents/irb-protocols-requiring-rsc-review-instructions-for-coordinators.pdf target=_blank > instructions or contact the Radiation Safety Officer at 977-6895.

X **Not Applicable**

Yes, study involves radioactive materials

2. Institutional Biosafety

Experiments involving the deliberate transfer of Recombinant or Synthetic Nucleic Acid Molecules (e.g., Gene Transfer), or DNA or RNA derived from Recombinant or Synthetic Nucleic Acid Molecules, or Microorganisms containing Recombinant or Synthetic Nucleic Acid Molecules and/or infectious agents (including select agents and toxins as defined by CDC and/or Animal and Plant Health Inspection Service (APHIS)) into one or more human research participants must be reviewed by the SLU Biological Safety Officer. Most of these protocols also require review and approval by the SLU Institutional Biosafety Committee (IBC). Please contact the SLU Biological Safety Officer at 977-6888 for more information.

X **Not Applicable**

Yes, study requires Institutional Biosafety review

3. Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee

Saint Louis University Hospital requires that all research involving the administration of medications within the hospital (including outpatient areas such as the Emergency Department, Outpatient Center, Saint Louis University Hospital-South Campus, etc.) be reviewed and approved by the Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee and that study drugs are received, stored, prepared, and dispensed by the Hospital's Department of Pharmacy Services. Please contact the Investigational Drug Services Clinical Pharmacist at 268-7156 or SLUH-IDS@ssmhealth.com for more information.

X **Not Applicable**

Yes, study requires PTNT review

4. Saint Louis University Hospital

All research involving Saint Louis University Hospital, including the Emergency Department, inpatient or outpatient services (including outpatient surgery at SLUH South Campus and the infusion center at the DOB) and medical record access, requires Research Business Review (RBR) and approval prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. While researchers can begin to complete the SSM RBR form at any time, the form should not be submitted until the IRB and the Clinical

Protocol Title: Effect of knee pain on walking biomechanics

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complete the SSM RBR form at any time, the form should not be submitted until the IRB and the Clinical Trials Office (CTO) have approved the study. Please contact the Research Compliance Office at 577-8113 or sluh-research@ssmhealth.com or the CTO at 977-6335 or clinical-trials-office@health.slu.edu for more information.

X **Not Applicable**

Yes, study requires Saint Louis University Hospital review

5. SSMSL

All research involving SSMSL locations (including Cardinal Glennon), including inpatient or outpatient services and medical record access, requires approval from the SSM STL or SSM Cardinal Glennon Research Business Review (RBR) prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. While researchers can begin to complete the SSM RBR form at any time, the form should not be submitted until the IRB and the CTO have approved the study. Please contact the SSMSL Office at 989-2058 or Marcy.Young@ssmhealth.com for more information.

X **Not Applicable**

Yes, study requires RBR review

6. **   Does this project require registration on ClinicalTrials.gov, and/or is this project subject to the NIH GCP Training Requirement? (Select "Yes" if either apply)** Y

Registration may be required if any of the following apply: 1) The project meets the FDAAA definition of an "Applicable Clinical Trial", which requires registration on ClinicalTrials.gov. 2) As of January 1, 2017, a new NIH policy mandated biomedical and behavioral "Clinical Trials" to be registered on ClinicalTrials.gov. In addition, NIH policies require personnel on NIH "Clinical Trials" to take GCP training every three years. 3) Registering may be required for Journal Publication (ICMJE). Please review relevant definitions here. Contact the CTO at clinical-trials-office@slu.edu with questions about registering on ClinicalTrials.gov and refer to the training page of the IRB website for information on NIH GCP Training requirements.

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* * * Subject Population * * *

8. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested)

a) **Expected age range of subjects. (For example ≥ 18 yrs to 90 yrs).**

Participants must be at least 45 years old to qualify.

b) **Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI).** 60 (30 in Knee OA cohort; 30 in Control cohort)

Exceeding the number listed here is a protocol violation. Prior IRB approval is required if additional participants are to be accrued. If applicable, this number should be consistent with your power analysis described in 3d.

c) **Number of evaluable subjects to be accrued study wide. *?HELP?*** 60

d) **If including vulnerable populations (minors, pregnant women and fetuses, neonates, non-English speaking, economically or educationally disadvantaged, prisoners, adults temporarily or permanently unable to consent for themselves): 1) provide the rationale for the importance of including this population in the research, and 2) specify the measures being taken to minimize risks to potentially vulnerable subjects. Click on hyperlinks to access SLU Guidelines containing additional considerations and strategies for mitigating risks.**

N/A, no vulnerable populations will be included in this study.

e) **If women, minorities, or minors are not included, a clear compelling rationale must be provided unless not applicable. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc. If federally funded reference appropriate section of the sponsors protocol/grant. *?HELP?***

Minors will not be included because knee OA is rare in minors and because the clinical definition of knee OA used in this study requires participants to be at least 45 years old.

f) **If any specifically targeted subjects are students, employees, or laboratory personnel, specify the measures being taken to minimize the risks and the chance of harm to these potentially vulnerable subjects. See SLU Guidelines for additional considerations and strategies for mitigating risks.**

g) **Describe (labeled a-c): a) who you are recruiting for this study (e.g., your patients/students/colleagues, those in existing database or registry, the general public), and b) how you are recruiting (flyers, advertisements, direct call/mailing, membership networks, in-person recruitment in clinic, classroom, public locations, etc.). For secondary data analysis or specimen studies, state how you have access to materials. Importantly: do not contact participants prior to obtaining IRB approval for your study.**

c) Also indicate whether or not you plan to obtain personal/private information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects prior to obtaining informed consent and how (obtained by communicating with prospective subjects or obtained by accessing records or stored biospecimens). Note: if you are accessing medical records other than those of your own patients or those in your immediate department, you will need to submit a <a href= https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/prep_to_research_form.doc target=_blank>HIPAA Preparatory to Research form and submit to the SLU Privacy Officer PRIOR to accessing records.

Please refer to the <a href=https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/guidelines_subject_recruitment.doc target=_blank>SLU IRB Recruitment Guidelines when designing recruitment strategies and upload recruitment materials to the Attachments page for IRB review. You are expected to obtain permission for individuals/organizations that assist with recruitment, and whenever possible, those assisting should share your materials with potential participants on your behalf rather than providing you with private contact information.

A) Patients as well as individuals from the St. Louis metropolitan area will be recruited for this study.

B) Potential participants will be recruited through advertisements, flyers, press releases, and word-of-mouth. Advertisements will be broadcasted through social media platforms, including Facebook and Instagram. Flyers will be distributed to local physician groups, foundations, health and wellness programs,

Instagram. Flyers will be distributed to local physician groups, foundations, health and wellness programs, fitness centers, community centers, and local businesses. Press releases will be performed by SLU Marketing and Communication (MarCom) services. Word-of-mouth recruitment will occur through personal interactions with St. Louis community members. Dr. Corrigan will also ask his physician colleagues to send out "Dear Patient" letters describing the study.

We will also utilize Washington University's Volunteer for Health (VFH) Recruitment Enhancement Core (REC) to assist with recruiting participants. This will be limited to posting on their social media platforms (i.e., Facebook, Instagram, and "X" formally Twitter) and posting to their website.

For all recruitment strategies, potential participants will be directed to fill out the Screening Form on REDCap as the first point of contact with the research team.

C) Individuals who are interested in participating in the study will fill out the online screening form. This screening form will be hosted by a database designed in Research Electronic Data Capture (REDCap) - a secure web-based, HIPAA-compliant and FDA-approved tool for collecting and analyzing data. In addition to answering questions that determine study eligibility (see inclusion/exclusion criteria), potential participants will be asked to provide their name, email address, phone number, and mailing address. The collection of this private information is necessary for bookkeeping, quality assurance, and mailing compensation to those who participate and opt to receive their payment by mail. No study-specific code numbers will appear in this database. Rather, screenings will be auto-numbered in the order they are received (1,2,3, etc.) then for those who enroll, records will be developed in the 'Master List' and 'Project Data' REDCap databases.

* * * Subject Population * * *

8. Subject Population (continued)

Page numbers from a sponsor's protocol/grant may be referenced in 8h.

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

Inclusion for Knee OA Cohort:
- at least 45 years old
- one knee that elicits at least 3 out of 10 pain with walking
- one knee with stiffness that lasts 0-30 minutes after periods of inactivity
- one knee with pain for at least the past 3 months
* Note -- same knee for items 2-4 above*

Inclusion for Healthy Cohort:
-at least 45 years old
- no lower body pain (greater than 1 out of 10 with walking) or injury within the past 6 months

Identify exclusion criteria.

Exclusions for Both Cohorts:
- history of knee replacement surgery
- opiate use within the past 3 months
- narcotic use within the past 3 months
- known medical condition that affects walking mechanics (besides knee OA for the Knee OA Cohort)
- known medical condition that affects pain perception
- inability to walk for 30 minutes without using an assistive device
- body weight greater than 300 pounds

- known allergy to adhesives
- high risk for a cardiovascular event (modified 2020 PAR-Q+)
-currently pregnant

Additional exclusions for Knee OA Cohort:
- anticoagulant use within the past 3 months
- intraarticular knee injection within the past 3 months
- known history of hypersensitivity to local anesthetics of the amide type
- history of lower body pain or injury, besides knee osteoarthritis, within the past 6 months
- Opposite knee has pain of greater than 1 out of 10 with walking
- Opposite knee has stiffness that lasts more than 30 minutes after periods of inactivity

i) Compensation. Explain the amount and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment.

Each participant in the Knee OA Cohort who completes the study will receive $100.00. Each participant in the Healthy Cohort (i.e., control group without knee OA) who completes the study will receive $50.00. Participants in the Healthy Cohort receive $50.00 less than those in the Knee OA Cohort because they complete two fewer visits (i.e., two visits compared to four visits). If participants do not complete the entire study, they will receive $25.00 for each completed visit. Participants will be paid in the amount owed to them with a single Amazon.com gift card at the end of their participation. Depending on the participant's preference, the gift card will either be transferred electronically via email or mailed to them. Regardless of the method of payment, gift cards will be sent to each participant within 4 weeks of their final visit.
All participants will also receive a parking voucher at each visit. Parking vouchers will allow participants to park in the visitor parking garage adjacent to the Allied Health Professions Building at no cost to them.

j) Describe who will cover study related costs. Explain any costs that will be charged to the subject.

Participants will not be responsible for any study costs. All research costs will be covered by the Academy of Orthopaedic Physical Therapy, the Rheumatology Research Foundation, Dr. Corrigan's faculty startup funds, or the Department of Physical Therapy and Athletic Training.

k) Estimate the probable duration of the entire study including data analysis and publication. This estimate should include the total time each subject is to be involved and the duration the data about the subject is to be collected. If the study is Investigator-initiated, a timeline for individual subject recruitment, follow-up, total time for subject accrual, and data analysis for the study is required.

The time each participant in the Knee OA Cohort may spend on this research study is approximately 6 hours over a 2-week period. (Four 1.5-hour visits with at least 2 days between visits)
The time each participant in the Healthy Cohort (i.e., control group without knee OA) may spend on this research study is approximately 3 hours over a 1-week period. (Two 1.5-hour visits with at least 2 days between visits)
It is expected that all visits will take approximately 1.5 hours, regardless of cohort allocation. In certain circumstances (e.g., equipment failure/malfunction) visits may last longer. No visit will last longer than 1.5 hours without agreement from the participant.

Anticipated Timeline:
- Subject Recruitment/Data Collections- September 2022-December 2023 (4 participants/month)
- Data Processing- September 2022-December 2023 (for each data collection, processing is expected to be completed within 1 week)
- Data Analyses- September 2023- January 2024
- Dissemination of Findings- Preliminary findings may be presented at professional conferences starting Fall of 2022. Peer-reviewed manuscripts will be prepared and submitted for publication within 12 months of the final data collection.
- Secondary analyses - Deidentified data will be leveraged indefinitely for answering additional research questions and providing preliminary data in future grant proposals.

Protocol Title: Effect of knee pain on walking biomechanics

*** * * Risks * * ***

9. Risks

There is no research that can be considered totally risk free (e.g., a potential risk of breach of confidentiality). Therefore, when describing the risk, the lowest level of risk is "no more than minimal risk".

Page numbers from a sponsor's protocol/grant may be referenced in 9.1, 9.2, 9.3, and 9.4.

1. **Use of investigational devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that subjects may experience while in the study.**

2. **Use of investigational drugs. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with placebos or washout periods that subjects may experience while in the study.**

3. **Use of FDA approved drugs, reagents, chemicals, or biologic products. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the package insert provided by the manufacturer. NOTE: Include any likely adverse effects associated with placebos or washout periods that subjects may experience while in the study.**

Adverse reactions for Lidocaine hydrochloride are provided below. For more information please see information and safety documents attached is section 16.

ADVERSE REACTIONS
Systemic
Adverse experiences following the administration of lidocaine HCl 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:

Central Nervous System
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.

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.

Cardiovascular System
Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

Allergic
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.

There have been no reports of cross sensitivity between lidocaine hydrochloride and procainamide or between lidocaine hydrochloride and quinidine.

Neurologic
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.

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.

There have been reported cases of permanent injury to extraocular muscles requiring surgical repair following retrobulbar administration.

Hematologic
Methemoglobinemia.

4. **Use of FDA approved devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that subjects may experience while in the study.**

During a diagnostic ultrasound examination, high frequency sound waves penetrate and interact with tissue in and around the area of anatomy to be imaged. Typical values of Center Frequency and Transmit Repetition Rate for these sound pulses are, respectively, from 1 to 20 MHz and from 1000 to 30000 pulses per second (1 KHz to 30 KHz).

Only a small portion of the sound energy of each pulse is reflected all the way back to the probe for use in constructing the image while the remainder is dissipated within the tissue. Although the

generation of biological effects (aka bioeffects) is intentional with therapeutic ultrasound, it is generally undesired in diagnostic applications and may be harmful in some conditions.

The interaction of sound energy with tissue at sufficiently high levels can produce bioeffects of either a mechanical or thermal nature. Mechanical bioeffects are primarily related to the pressure amplitude of individual pulses. Thermal bioeffects are primarily related to absorbed energy, and therefore contributing factors are the amplitude and length of the pulses, as well as the spatial distribution and repetition rate of the acoustic pulse stream, and the overall dwell times of the exam.

The American Institute of Ultrasound in Medicine (AIUM) has published the following statement on the Safety of Research Using Diagnostic Ultrasound: "Diagnostic ultrasound has been in use since the late 1950s. There are no confirmed adverse biological effects on patients resulting from this use. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in research, experience from normal diagnostic practice may not be relevant to potential extended exposure times and altered exposure conditions in research. It is therefore considered appropriate to make the following recommendation: When examinations are carried out for purposes of research, ultrasound exposures should be as low as reasonably achievable (ALARA) within the goals of the study. In addition, informed consent, using a form approved by an Institutional Review board, should be obtained from the patient. Informed consent forms should include information about the anticipated exposure conditions and how these compare with normal diagnostic practice. Repetitive and prolonged exposures on a single patient should be justified and consistent with prudent and conservative use."

5. Describe any risks related to performing study procedures. Please include all investigational, non-investigational, and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

The following are potential risks associated with participating in this study.
1. Local discomfort, infection, and/or nerve damage during injections (Knee OA Cohort only)
2. Discomfort or lightheadedness from prolonged standing during preparation phase of motion analysis
3. Slipping or falling while walking on the treadmill
4. Loss of privacy during data collection
5. Increased knee pain (Knee OA Cohort only)
6. Skin irritation when removing motion capture markers (i.e., reflective plastic balls)
7. Soreness and/or stiffness in lower body joints and muscles
8. Loss of confidentiality
9. Side effects and/or adverse reactions to the study drug, lidocaine hydrochloride.
10. Discomfort with the functional near-infrared spectroscopy (fNIRS) cap.

6. Describe any risks related to the use of radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy).

7. Describe why this investigational compound/drug/device/procedure's risks/benefits are potentially better than standard of care or other common alternatives. Any standard treatment that is being withheld must be disclosed and the information must be included in the consent form. *?HELP?*

This study is not intended to provide treatment to participants. Furthermore, this study should not prevent participants from receiving treatments for their condition.

8. **Describe any psychological, social, or legal risks the subject may experience. *?HELP?***

There is a risk of loss of confidentiality.

Page numbers from a sponsor's protocol/grant may be referenced in 9.9 and 9.10.

9. **Special Precautions. Describe the planned procedures for protecting against or minimizing potential risks. If appropriate, include the standards for termination of the participation of the individual subject. Discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.**

Protection against the potential risks are as follows:
1. Local discomfort, infection, and/or nerve damage during injections. (Knee OA Cohort only) Local discomfort during and immediately following the injections is expected to be minimal and resolve within 2-3 minutes, similar to receiving a flu shot. Discomfort will be monitored by Dr. Neme for 15 minutes post-injection and then by Dr. Corrigan for the remainder of each visit. Infection is very uncommon with knee injections. In order to reduce the likelihood of infection, we will use sterile procedures, which includes using sterile needles and syringes and preparing the skin with an antiseptic (e.g., betadine). Nerve damage is also possible, yet we will use ultrasound imaging to guide the injection into the knee joint, making the possibility of nerve damage highly unlikely. If signs or symptoms of infection or nerve damage occur, the participant will be recommended to seek medical attention.

2. Discomfort or lightheadedness from prolonged standing during preparation phase of motion analysis. To minimize this risk, participants will be instructed to occasionally bend their knees and shift their body weight. If a participant becomes lightheaded, proper medical care will be provided including lying down and monitoring vital signs. If additional medical care is necessary an ambulance will be summoned.

3. Slipping or falling while walking on the treadmill. Participants will be educated on the use of the treadmill prior to walking. Safety will be ensured by gradually increasing the speed of the treadmill and discussing comfort level. Participants will also wear a fall-safety harness while walking on the treadmill and be instructed to remain within arms-reach of the hand rail. If a participant slips or falls, study staff 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 study staff as needed. If further immediate attention is needed, an ambulance will be summoned. Regardless of the severity, study staff will follow-up with the participant the following day to ensure appropriate care was received and to determine next steps in study participation.

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 testing. To minimize this risk, signs will be posted outside the lab requesting privacy during testing.

5. Increased knee pain. (Knee OA Cohort only) It is highly likely that participants in the Knee OA Cohort will experience fluctuating pain throughout the study, as this is a typical presentation of knee OA and the protocol is designed to change pain severity. Study staff will closely monitor pain severity throughout the study. If a participant's pain increases to a point where they request to stop walking, testing will be stopped immediately and the participant will not perform any remaining physical tests/procedures. Regardless of pain severity, at the end of each visit, participants will be offered a bag of ice for short-term pain relief.

6. Skin irritation when removing motion capture markers (i.e., reflective plastic balls). Irritation is generally caused by minor reactions to adhesive or when leg hair is pulled out with the adhesive. This process is comparable to removing a band-aid in a hairy location of the body. In Dr. Corrigan's experience, very few people experience irritation that last longer than a few minutes. If a participant experiences lasting irritation, study staff will recommend over-the-counter ointments and determine appropriateness of continued participation.

7. Soreness and/or stiffness in lower body joints and muscles. The study protocol involves walking at different speeds, gradients, and durations. These different types of walking may be unfamiliar to participants and cause soreness and/or stiffness throughout the body, particularly after testing has been completed. This is normal physiologic response to exercise. To reduce the likelihood of excessive soreness or stiffness, participants will be given 2-minute breaks between the different walking conditions. Furthermore, there will be a minimum of 2 days between visits so the likelihood of soreness or stiffness during testing is unlikely. However, if a participant experiences soreness/stiffness that is disabling and either lasts longer or is more severe than expected, study staff will recommend they seek medical attention prior to continuing participation in the study.

8. Loss of confidentiality. 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 10 years, your personal information will be destroyed, leaving only de-identified data.

Throughout the study, Research Electronic Data Capture (REDCap) will be used for collecting, managing, and storing your study record. 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.

9. Side effect to lidocaine hydrochloride. Researchers will be using a drug called Lidocaine Hydrochloride to numb the participants knee joint. Although it is unclear how often side effects occur, it is recommended for individuals to seek medical attention if they 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, researchers will monitor the participants closely for any side effects. If any occur, researchers will help them seek immediate medical advice and attention.

10. Discomfort with fNIRS cap. The cap is designed to be snug and the diodes can exert some pressure on the scalp. This improves data quality. The research team will attempt to minimize discomfort by adjusting diode pressures and measuring head size. Although we expect to be able to make adjustments to the cap to minimize discomforts, if a participant reports continued discomfort, fNIRS will not be completed.

Participants may be withdrawn from the research study. Potential reasons for withdrawal include:
1) knee pain worsens to a point where alternative treatment is medically indicated
2) A side effect or medical condition occurs that may place the participant at risk of further complications
3) Inability to participate as instructed
4) Inability to keep scheduled appointments
5) Cancellation of the research study by sponsor or regulatory agency.

Participant safety will be closely monitored by the study staff throughout the project. Participants will be advised to contact Dr. Corrigan if they wish to discuss any issues that arise outside of data collection visits. Dr. Corrigan will follow all protocols and procedures for managing and reporting unanticipated problems and adverse events.

10. Reproductive Risks.

a. Please list the pregnancy category of any drugs or N/A.

N/A

b. Please describe any reproductive risk associated with any part of the research study. Include any data from other studies (animal or human).

N/A

11. Data Safety Monitoring

Federal regulations require that when appropriate, the research protocol makes adequate provisions for monitoring the data to ensure the safety of participants. Monitoring should be commensurate with risks and with the size and complexity of the research, and could range from no plan needed to an independent data safety monitoring board. Please refer to SLU Guidelines for Data and Safety Monitoring as you complete the questions below.

a. Is there a Data Monitoring Committee (DMC) or Board (DSMB)? N

If yes, please provide the following information (labeled a-g): a) the composition of the board (degrees/qualifications of members), b) whether the board is independent from the sponsor and research team or not, c) frequency of meetings and issuance of reports to sites, d) assurance that the board is reviewing aggregate safety data and making recommendations regarding study continuance, e) provisions for ad hoc meetings if needed, f) who is reviewing SAEs in real time (MD or DO), and g) stopping/halting rules (if any exist).
A DSM charter can be referenced for all items except for "f) who is reviewing SAEs in real time."

If no, please justify why not.

SAEs are highly unlikely for this research project. All of the research methodologies used in this study are minimal risk. Furthermore, knee injections with lidocaine hydrochloride are routinely performed in clinical practice with minimal risk.

b. Is there a Data Safety Monitoring Plan (DSMP)? Y

Note, if all relevant plan information is included in DSMB question above, select 'Yes' and state "see above" in the answer box.

If yes, provide details (labeled a-e) including: a) what types of data or events are captured and how are they documented, b) who is monitoring data, their independence/affiliation with the research and their degrees/qualifications, c) frequency of aggregate data review, d) who is reviewing SAEs in real time (MD or DO), and e) stopping/halting rules (if any exist).

a) adverse events and unanticipated problems will be captured during study visits and when a participant directly contacts either Dr. Corrigan or SLU's IRB. They will be documented by submitting adverse event and/or unanticipated problem documents in SLU's IRB portal. Additionally, forms will be de-identified and uploaded into the participants record in the project's REDCap database.
b) As the principal investigator, Dr. Corrigan will be the primary individual responsible for data monitoring. Dr. Gretchen Salsich, will monitor adverse events and unanticipated problems alongside Dr. Corrigan. Dr. Salsich is ideal for this role because she is Dr. Corrigan's faculty research mentor and experienced in conducting biomechanical research at SLU.
c) Drs. Corrigan and Salsich will perform aggregate data review on a monthly basis.
d) SAEs are highly unlikely, but in this situation Drs. Corrigan, Salsich, and Neme will review in real time.
e) No stopping or halting rules exist. If a SAE occurs, Dr. Corrigan will work with Dr. Salsich, Dr. Neme, and the SLU IRB to generate stopping and halting rules.

If no, please justify why not.

12. In case of international research (research outside of the U.S. or research on international populations (non-U.S.)), describe qualifications/preparations that enable you to evaluate cultural appropriateness and estimate/minimize risks to subjects. Include whether research is sensitive given cultural norms.

a. State any local laws/regulations governing Human Subjects Research in the country(ies) you will conduct the research and attach any relevant approvals. If none, state N/A.

b. Will there be language barriers and if so, how will they be addressed?

Note: If materials are to be distributed to subjects in their native language, please follow SLU's Guidance For Studies Involving Non-English Speaking Subjects.

          NOTE: Export control laws include the transfer of technical information and data, as well as information
          and technology to foreign nationals. If this study has international components, contact the SLU Export
          Control Officer for direction on whether export control policies apply.

Protocol Title: Effect of knee pain on walking biomechanics

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* * * Benefits/Alternatives, Procedures to Maintain Confidentiality and Privacy * * *

10. Benefits/Alternatives

a) **Benefits. Describe the potential benefit(s) to be gained by the subjects and how the results of the study may benefit future subjects and/or society in general. Indicate if there is no direct benefit to the participants.**

Participants may not benefit from participating in this research study. Participants' condition may get better, stay the same, or worsen.

Even though participants may not benefit from participating in this study, findings from the current study are likely to inform future research that leads to improved outcomes for persons with knee OA.

b) **Alternatives. Describe any alternative treatments and procedures available to the subjects should they choose not to participate in the study. If no such alternatives exist, please state that the alternative is nonparticipation. For some studies, such as record reviews, a description of alternatives would not be applicable.**

The alternative to participation is nonparticipation. No other treatments or procedures will be offered to individuals who chose not to participate.

11. Procedures to Maintain Confidentiality and Privacy

Federal regulations require that research materials be kept for a minimum of three (3) years and HIPAA documents be kept for a minimum of six (6) years after the closure of the study. For FDA-regulated or sponsored projects, the PI may be required to keep the data and documents for a longer time period.

Confidentiality

To determine whether adequate provisions for confidentiality of data are in place, the IRB must ensure that research materials are stored in appropriate locations throughout the study (during collection, transport/transmission, analysis and long term storage). Research information must be protected using appropriate safeguards based on identifiability of the data and risk associated with the study (See SLU IRB Confidentiality Guidelines).

For the questions below, please use the following definitions:

Anonymous/De-identified: data contain no identifiers, including code numbers that investigators can link to individual identities;

Coded: data in which (1) identifying information, such as name or social security number, has been replaced with a number, letter, symbol, or combination thereof (i.e., the code), and (2) a key to decipher the code exists enabling linkage of data to identifying information (e.g., a master list), and (3) the key (master list) is kept separately from coded data; AND/OR

Identifiable: data that includes personal identifiers (e.g., name, social security number), such that information could be readily connected to respective individuals.

a) Electronic (Computer) Data

Click "Add" to enter data security information for each type of electronic data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data. See the SLU ITS Sensitive Data Guide for acceptable data security methods.

Not Applicable, No Electronic (Computer) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Electronic Data

Type of Data	Storage Location	Data Transmission Outside of SLU	Supplemental information related to above items can be entered here or leave blank:
Coded	SLU ITS managed device (computer, tablet, etc.) with encryption; SLU ITS network storage (T: drive (shared drive), U: drive (personal drive)); Collection or Storage of data in SLU REDCap	Not Applicable, I will not be sending/sharing electronic data outside of SLU	The master list REDCap database will be coded, including only the code number and the screening number. Survey/Questionnaire data will be collected directly in the project's REDCap database. Motion capture data files will be collected on SLU ITS managed devices with encryption, then backed up on ITS networks (T and/or U drives). After determined from motion capture data files, measures will be recorded and in the project's REDCap database. Ultrasound data will be collected with the ultrasound scanner. At the end of each visit, ultrasound data will be transferred to a SLU ITS managed device with encryption and backed up on ITS networks (T and/or U drives). After imaging processing, measures will be recoded in the project's REDCap database.
Identifiable	Collection or Storage of data in SLU REDCap	Not Applicable, I will not be sending/sharing electronic data outside of SLU	The screening REDCap database will include questions for determining eligibility as well as name, phone number and/or email, and mailing address.

b) Hardcopy (Paper) Data

Click "Add" to enter information for each type of hardcopy (paper) data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data.

Not Applicable, No Hardcopy (Paper) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Hardcopy Data

Type of Data	Storage Location	Transported Data Security	Supplemental information related to above items can be entered here or leave blank:
Identifiable	SLU Locked Cabinet; SLU Locked Room/Office	N/A	Consent forms will be the only hardcopy documents for the study.

c) If a master list is used in this study (linking study codes to subject identifiers), explain: a) how and where you will secure the master list, b) how long it will be kept/when it will be destroyed, and c) provide a sample of the code.

This study will use three separate REDCap databases. One will be a screening database, which includes a screening number (145), subject identifiers (name, phone, email, mailing address), and questions for screening (see attached screening form). The second will be a project database, which includes the code number (e.g., KP05), and the participants data. The third will be a master list database, which will simply pair the screening and code numbers (i.e., Data for KP05 is from Screen 145). In this way, subject identifiers are never connected with the code number and data, and all three database would be required to decipher an individuals data. Three years after the study is completed, the master list database will be destroyed, effectively removing the link between participant identities and study data. As for the screening database, individual records will be destroyed three years after the study is completed for all entries except those who enrolled and consented to be contacted for future research.

d) If data or specimens are being shared outside of the research team, indicate who will receive the material, specifically what they will receive (data or specimens), and if an agreement has been signed to cover the transfer. Note: unless covered under a Clinical Trial or other agreement, the transfer of data or specimens to an external entity will require an agreement. For the transfer of materials (specimens), a Materials Transfer Agreement (MTA) is used; for the transfer of data, a Data Use or Data Transfer Agreement is used. Please contact the Research Innovation Group at 314-925-3027 for assistance.

De-identified data will be shared with the following personnel:
David Felson: Boston University School of Medicine
Tuhina Neogi: Boston University School of Medicine
Cara Lewis: Boston University
Michael LaValley: Boston University
Irene Davis: Harvard University
Joshua Stefanik; Northeastern University

e) If samples or data will be provided to SLU from an outside source, indicate whether you will have access to identifiers, and if so, how identifiable information is protected. Note: unless covered under another agreement (e.g., Clinical Trial Agreement or subcontract), the transfer of data or specimens from an external entity to SLU may require an agreement. For the transfer of materials (specimens), a Materials Transfer Agreement (MTA) may be required; for the transfer of data, a Data Use or Data Transfer Agreement may be required. Please contact the Research Innovation Group at 314-925-3027 for assistance.

N/A

f) If data will be collected via e-mail or the Internet, how will anonymity or confidentiality be affected? Describe how data will be recorded (i.e., will internet protocol (IP) addresses and/or e-mail addresses be removed from data?).

The internet will be used by potential participants who fill out the REDCap screening form. Additionally, during data collection visits, a member of the research team will use the internet to login to their REDCap account, access the appropriate project and record, then the participant will answer questionnaires/surveys directly into their own record. Loss of confidentiality or anonymity is unlikely by using SLU's secure REDCap database only.

g) If you will be audio/video recording or photographing subjects, provide a rationale as voiceprints and images of faces/unique body markings are considered identifiers. Describe confidentiality procedures, including any restricted access to images and/or the final disposition of the recordings/photos (destruction, archiving, etc.).

Photos and/or videos of study tasks and procedures will be obtained for educational and dissemination purposes. Photos and videos will only be obtained from participants who consent. No videos or photos will include the participant's face. If the participant has unique body markings, photos and/or videos will not be taken. All video and photos will be stored without code or screening numbers to maintain confidentiality and privacy. Additionally, all videos and photos will be stored on secure SLU ITS Servers (T and/or U Drives).

h) Describe any study-specific (non standard of care) information or documentation that will be put in the participants' medical records for this research (e.g., study visit notes, lab results, etc.). If none, state "not applicable". NOTE: documentation of research in Epic should be done in accordance with the SLUCare Epic Research Charting Policy and Clinical Workflow: Documenting Research Encounters in Epic.

N/A

i) Are there any information security requirements identified in the project's RFP/Award Notice/Contract? This could include data security, technical safeguards, security controls, NIST, FISMA, CFR, etc. N

If yes, SLU ITS approval is required. Contact InfoSecurityTeam@slu.edu to start the approval process.

Privacy

Privacy refers to persons having control over the sharing of oneself with others.

j) Please indicate how participant privacy will be protected in this study (select all that apply):

X Discussion of health related and/or personal information in a private room/area

X Research interactions/interventions are conducted in a private room/area

X Use of drapes or other privacy measures

X Collection of sensitive/identifiable information is limited to the minimum necessary to achieve the aims of the research

X Access to study information is limited to the minimum amount of persons necessary to achieve the aims of the research (e.g., access restricted to research team members only)

Consideration of parental inclusion/absence for studies involving minors

Other (please explain):

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* * * Potential Conflict of Interest * * *

12. Potential Conflict of Interest

Indicate whether you, your spouse or dependent children, have, or anticipate having, any income from or financial interest in a sponsor, device or drug manufacturer of this protocol, or a company that owns/licenses the technology being studied. Please remember that you are responding for you and any other investigator participating in the study. Financial Interest includes but is not limited to: consulting; speaking or other fees; honoraria; gifts; licensing revenues; equity interests (including stock, stock options, warrants, partnership and other equitable ownership interests). For questions regarding Conflict of Interest consult the Conflict of Interest in Research Policy.

Check one of the following (please remember that you are responding for yourself, your spouse, dependent children and any investigator, investigator's spouse and dependent children participating in the study):

1) X No equity interest and/or Financial Interest less than or equal to $5K
2) Any equity interest and/or Financial Interest exceeding $5K but not exceeding $25K in the past year or expected in the current year
3) Financial Interest exceeding $25K in the past year or expected in the current year

Check all those that apply:

Consulting
Speaking Fees or Honoraria
Gifts

Licensing agreement or royalty income

Equity interests, (including stock, stock options, warrants, partnership or equitable ownership interests), or serving on a scientific advisory board or board of directors

Other fees/compensation

If you have marked #2 or #3, please contact coi@slu.edu to initiate review of this study and provide the following information:

1. A Conflict of Interest Management Plan.
   - has been approved for all investigators for this study
   - is pending
   - has not been initiated

2. Describe who has, and briefly explain, the conflict of interest and indicate specific amounts for each subcategory checked:

Note to Investigator(s) Reporting a Potential Conflict of Interest

Investigator(s) must have:

1. Current, up-to-date Conflict of Interest Disclosure Form on file with the SLU Conflict of Interest in Research Committee (COIRC) that describes any financial relationship indicated above.

   . This information must be disclosed on the SLU confidential Conflict of Interest Disclosure Form and reviewed by the COIRC before accruing research subjects in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated Disclosure Form to the COIRC.

2. You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the COIRC for this study. To initiate COIRC review of your study, please contact coi@slu.edu.

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* * * Informed Consent * * *

13. Informed Consent

Federal regulations require that informed consent be obtained from individuals prior to their participation in research unless the IRB grants a waiver of consent. Answer the questions, below, then click Add to provide the necessary consent documents and information regarding subject consent. Multiple consents/waivers may be added, but they must be uploaded one at a time.

NOTE: You may refer to the SLU IRB Guidance for Obtaining Informed Consent for considerations

regarding the consent/assent process.

State N/A if not applicable.

1) How is consent being obtained? When and where will the discussion take place? If the study involves a Non-English Speaking participant/population, please include details about plans for translated consent materials and interpreters to be used (see SLU Guidelines for Involving Non-English Speaking Subjects for more details).

The consenting process will be completed by Dr. Corrigan or a member of the research team at the potential participant's first visit in a semi-private office located within the private lab space. As part of this process, Dr. Corrigan or a member of the research team will re-screen the potential participant to ensure eligibility, go through the entire consent form, and answer any questions. After Dr. Corrigan or a member of the research team has fielded their questions, the potential participant decides whether or not they will participate. If the potential participant decides to participate in the study, they will be asked to sign the consent form. A signed copy of the consent form will be provided to the participant. If the potential participant decides not to participate in the study, they will not sign the consent form or complete any study procedures.

2) If the study involves adults unable to consent for themselves (whether diminished capacity to consent is temporary, permanent, progressive or fluctuating), please address the following: a) how is capacity to provide consent being assessed (initially and throughout study, if applicable); b) if unable to provide consent, how is LAR being determined (See SLU LAR Guidelines); c) if unable to provide consent, will assent be obtained and if not, why not?; d) if unable to provide assent, will dissent be honored and if not, why not? Note: participants initially unable to provide consent for themselves are expected to be given an opportunity to provide consent once capacity is gained. See SLU Guidelines for Adults Unable to Provide Consent for additional detail.

N/A

Note: Any assent documents which will be used per the Adults Unable to Provide Consent guidance, should be appropriately named and uploaded using the Add button and the Consent drop down menu selection.

Informed Consent

Title	Consent Type	Attached Date
Approved_Informed Consent -- Version 5 -- Clean	Consent	03/01/2023
Approved_CR2023_Informed Consent_v5_clean	Consent	12/19/2023

* * * Assent * * *

14. Assent

Complete this section if your study includes minors. The Assent Form Templates (For children and For adolescents) provide guidelines for writing the assent document.

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1. Will minors be asked to give assent, then consent once they reach adulthood? If not, please justify. If not capable to provide assent initially, please address whether assent will be obtained as the minor gains capacity. Note: children who reach the age of adulthood during participation should be given the opportunity to provide consent as parent/guardian consent no longer applies. If obtaining consent would be impracticable (e.g., this is a registry with data/specimen obtained long ago), a waiver of consent should be added for IRB review. See SLU Guidelines for Research Involving Minors for additional detail.

2. If minors are asked to assent and do not wish to participate, will they still be accrued in the study? If yes, justify.

3. How will the minor's ability to give assent be assessed? (Consider the age and maturity of the minors as well as their physical or mental condition). If capacity is fluctuating, please explain how capacity will be assessed throughout the study.

Note: For studies that require a discussion about reproductive risks, note that the conversation with the minor should take place separately from the parents. Also, if a minor will reach adulthood (18 in Missouri) during the course of the study, they will need to be asked to consent as an adult at that time to continue in the study.

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* * * HIPAA * * *

15. HIPAA

Studies that access, receive or collect protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information refer to the SLU IRB HIPAA Guidance.

1. Will health information be accessed, received or collected?

   No health information. HIPAA does not apply.

   X Yes (continue to question 2).

2. Which personal identifiers will be received or collected/recorded?

   No identifiers. I certify that no identifiers from the list below will be received or collected and linked to health information. (Skip remainder of page).

   Limited identifiers will be received or collected/recorded (study will likely require a data use agreement). Select Data Use Agreement- INTERNAL or Data Use Agreement- EXTERNAL as appropriate, below.

   City/State/Zip codes

   Person-specific dates (e.g., date of birth, dates of service, admission/discharge dates, etc.)

   Age (if subjects are 90+ years)

   X At least one direct identifier will be received or collected/recorded.

   X Names

	Social Security numbers
X	Telephone numbers
	Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)
X	All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000
X	All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
	Fax numbers
X	Electronic mail addresses
	Medical record numbers
	Health plan beneficiary numbers
	Account numbers
	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers and serial numbers
	Web Universal Resource Locations (URLs)
	Internet Protocol (IP) address numbers
	Biometric identifiers, including finger and voice prints
	Full face photographic images and any comparable images

If you are receiving or collecting/recording health information and at least one personal identifier, please continue to complete the sections, below.

3. Sources of Protected Health Information:

	Hospital/medical records for in or out patients
	Physician/clinic records
	Laboratory, pathology and/or radiology results
	Biological samples
X	Interviews or questionnaires/health histories
	Mental health records
	Data previously collected for research purposes
	Billing records
	Other

Please describe:

4. If data will be shared outside the research team and the study involves PHI indicate how the research

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team will share the information.

X Not applicable (continue to question 5).

Only linkable code that can link data to the identity of the subject. A code access agreement or business associate agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below.

Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below, using DUA-external option.

With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

5. **HIPAA Documentation is required for this study. Use the table below to add HIPAA Documents for your study.**

HIPAA Documents

HIPAA Documents	Title	Attached Date
HIPAA Authorization	Approved_HIPAA Authorization Form - Version 2 - Clean	03/03/2022

*** * * Attachments * * ***

16. Attachments

In this section, please upload additional documents associated with your protocol. Failure to attach files associated with the protocol may result in the protocol being returned to you.

Possible documents for this protocol could include:

- **Bibliography**
- **Cooperating Institution's IRB Approval**
- **Data Collection Sheet**
- **Debriefing Script**
- **Device Information/Documentation**
- **Grant Proposal/Sub-Contract**
- **Human Subjects Training Certificate/Proof of Training**
- **Information Sheet/Brochure**
- **Interview/Focus Group Questions**
- **Investigator's Brochure**
- **Letter of Agreement/Cooperation**

- **IND Application Letter**
- **Package Insert**
- **Patient Diary Form**
- **Questionnaire/Survey**
- **Recruitment Material (e.g., flyers, ads, e-mail text)**
- **Safety Information (DSM Information)**
- **Scientific/PPC Review or Department Chair Review**
- **Sponsor's Protocol**
- **Sponsor's Protocol Amendment**
- **Study Design Chart/Table**
- **Other files associated with the protocol (most standard formats accepted: pdf, jpg, tiff, mp3, wmv, etc.)**

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

Document Type	Document Name	Attached Date	Submitted Date
Grant Proposal/Sub-Contract	AOPT Funded Grant Proposal	12/06/2021	12/07/2021
Grant Proposal/Sub-Contract	RRF Funded Grant Proposal	12/06/2021	12/07/2021
Package Insert	Lidocaine Package Slip	12/07/2021	12/09/2021
Human Subjects Training Certificate/Proof of Training	Patrick Corrigan CITI Training Certificate	12/07/2021	12/09/2021
Bibliography	Bibliography	12/08/2021	12/09/2021
Device Information/Documentation	User Manual for Ultrasound Scanner	12/08/2021	12/09/2021
Safety Information (DSM Information)	Safety Information for Lidocaine HCl	12/08/2021	12/09/2021
Scientific/PPC Review or Department Chair Review	Scientific Pre-Review Form	12/09/2021	12/09/2021
Human Subjects Training Certificate/Proof of Training	Patrick Corrigan CITI Completion Report	12/09/2021	12/09/2021
Device Information/Documentation	K211488	01/26/2022	02/15/2022
Grant Proposal/Sub-Contract	AOPT Approved Deferral and Change of Institution	02/15/2022	02/15/2022
Grant Proposal/Sub-Contract	AOPT Grant Agreement	02/15/2022	02/15/2022
Grant Proposal/Sub-Contract	AOPT NOA	02/15/2022	02/15/2022

Grant Proposal/Sub-Contract	RRF Approved Change of Institution	02/15/2022	02/15/2022
Grant Proposal/Sub-Contract	RRF Approved Deferral	02/15/2022	02/15/2022
Grant Proposal/Sub-Contract	RRF Deferral Approval	02/15/2022	02/15/2022
Grant Proposal/Sub-Contract	RRF NOA	02/15/2022	02/15/2022
Questionnaire/Survey	Approved_Study Questionnaires	03/03/2022	03/03/2022
Questionnaire/Survey	Approved_Demographics Form	03/03/2022	03/03/2022
Recruitment Material (e.g., flyers, ads, e-mail text)	Approved_Recruitment Conversation/Statement	03/03/2022	03/03/2022
Recruitment Material (e.g., flyers, ads, e-mail text)	Approved_ScreeningForm	03/03/2022	03/03/2022
Human Subjects Training Certificate/Proof of Training	Aaron CITI training certificate	08/31/2022	09/02/2022
Questionnaire/Survey	Approved_Demographics_EffectOfKneePainO	10/21/2022	10/21/2022
Questionnaire/Survey	Approved_GeneralMedicalHistory_EffectOf	10/21/2022	10/21/2022
Questionnaire/Survey	Approved_KneeSpecificSurvey_EffectOfKnee	10/21/2022	10/21/2022
Questionnaire/Survey	Approved_LeftKoos_EffectOfKneePainOnWal	10/21/2022	10/21/2022
Questionnaire/Survey	Approved_PASBQ_EffectOfKneePainOnWalkin	10/21/2022	10/21/2022
Questionnaire/Survey	Approved_PreviousMusculoskeletalInjurie	10/21/2022	10/21/2022
Questionnaire/Survey	Approved_RightKoos_EffectOfKneePainOnWa	10/21/2022	10/21/2022
Questionnaire/Survey	Approved_Screening form	10/21/2022	10/21/2022
Questionnaire/Survey	Approved_Study Description screening instructions	10/21/2022	10/21/2022
Questionnaire/Survey	Approved_TreadmillComfort_EffectOfKneeP	10/21/2022	10/21/2022
Questionnaire/Survey	Approved_VasScale_EffectOfKneePainOnWal	10/21/2022	10/21/2022
Recruitment Material (e.g., flyers, ads, e-mail text)	Approved_Facebook_Ad	10/21/2022	10/21/2022
Recruitment Material (e.g., flyers, ads, e-mail text)	Approved_Injection Study Flyer - final	10/21/2022	10/21/2022

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Human Subjects Training Certificate/Proof of Training	Kaila Fennell Citi Training Certificate	01/20/2023	02/08/2023
Package Insert	fNIRS Package Insert	02/25/2023	02/25/2023
Questionnaire/Survey	Approved_ICOAPQuestionnaire_EffectOfKne	03/01/2023	03/01/2023
Questionnaire/Survey	Approved_PROMISScaleV10PainIntensity3a_	03/01/2023	03/01/2023
Questionnaire/Survey	Approved_PROMISSFV10PainInterference6b_	03/01/2023	03/01/2023
Recruitment Material (e.g., flyers, ads, e-mail text)	Approved_Dear patient letter_PC	03/01/2023	03/01/2023
Human Subjects Training Certificate/Proof of Training	Megan_CITI_Cert	04/25/2023	04/25/2023
Human Subjects Training Certificate/Proof of Training	Lara_CITI_Cert	04/25/2023	04/25/2023
Human Subjects Training Certificate/Proof of Training	Patryk _CITI_Cert	04/25/2023	04/25/2023
Human Subjects Training Certificate/Proof of Training	Hailey_CITI_Cert	04/25/2023	04/25/2023
Recruitment Material (e.g., flyers, ads, e-mail text)	Approved_HealthyParticipant_Flyer	05/03/2023	05/03/2023
Recruitment Material (e.g., flyers, ads, e-mail text)	Approved_32283_Press_Release	07/05/2023	07/05/2023
Safety Information (DSM Information)	Data Safety Monitoring Report	12/13/2023	12/13/2023
Human Subjects Training Certificate/Proof of Training	Sharf_CITI_Cert	01/23/2024	03/05/2024

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* * * PI Obligations * * *

PI Obligations

By clicking the box below you indicate that you accept responsibility for and will follow the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code, and the Ethical Principles of the American Psychological Association (if applicable) for the research described. It also indicates that you have the requisite funding, credentials, training, and any necessary hospital privileges, if needed, to carry out all procedures and treatments involved in the protocol.

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Clicking the box also affirms that the activities involving human subjects will not begin without prior review and approval by the Institutional Review Board, and that all activities will be performed in accordance with state and federal regulations and Saint Louis University's assurance with the Department of Health and Human Services. The PI assures that if members of the SLU research team access protected health information (PHI) from a covered entity in order to seek consent/authorization for research or to conduct research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered entity without IRB authorization or approved waiver. PI further assures that the SLU research team will comply with the terms of a Data Use Agreement to PHI (if any).

1) Have you completed the annual Conflict of Interest in Research Disclosure Form? Y

You can only select N/A if you are not currently listed on any externally funded research projects nor listed on any proposals for externally funded research support.

NOTE: An annual disclosure must be completed by all faculty, staff and students involved in the design, conduct or reporting of externally funded research applications and awards.

2) Have your financial interests changed significantly since you completed the annual disclosure form? N

The PRINCIPAL INVESTIGATOR certifies that he/she has read the University's Conflict of Interest Research Policy and has checked the appropriate box in the 'Potential Conflict of Interest' section of the application. In addition, the PRINCIPAL INVESTIGATOR certifies that, to the best of his/her knowledge, no person working on this project at SLU has a conflict of interest or if a conflict of interest does exist, that an appropriate management plan is in place.

According to the Saint Louis University Conflict of Interest in Research Policy, as PI, it is your responsibility to inform co-investigators, staff, or students involved in the design, conduct, or reporting of externally sponsored research of their requirement to complete a Conflict of Interest in Research Disclosure Form.

X **I accept this responsibility.**

X **The Principal Investigator has read and agrees to the above certifications and will abide by the above obligations.**

*** * * Event History * * ***

Event History

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Date	Status	View Attachments	Letters
04/29/2024	REPORT 1 FORM APPROVED	Y	Y
04/22/2024	REPORT 1 FORM REVIEWER(S) ASSIGNED		
04/22/2024	REPORT 1 FORM REVIEWER(S) ASSIGNED		
04/11/2024	REPORT 1 FORM SUBMITTED	Y	
04/09/2024	REPORT 1 FORM CREATED		
03/21/2024	AMENDMENT 7 FORM APPROVED	Y	Y
03/13/2024	AMENDMENT 7 FORM REVIEWER(S) ASSIGNED		
03/12/2024	AMENDMENT 7 FORM PANEL REASSIGNED		
03/12/2024	AMENDMENT 7 FORM PANEL MANAGER REVIEW		
03/12/2024	AMENDMENT 7 FORM PANEL REASSIGNED		
03/05/2024	AMENDMENT 7 FORM SUBMITTED	Y	
01/18/2024	AMENDMENT 7 FORM CREATED		
12/19/2023	CONTINUING REVIEW 2 FORM APPROVED	Y	Y
12/11/2023	CONTINUING REVIEW 2 FORM SUBMITTED (CYCLE 1)	Y	
11/27/2023	CONTINUING REVIEW 2 FORM REVIEWER(S) ASSIGNED		
11/27/2023	CONTINUING REVIEW 2 FORM PANEL MANAGER REVIEW		
11/27/2023	CONTINUING REVIEW 2 FORM PANEL REASSIGNED		
11/24/2023	CONTINUING REVIEW 2 FORM SUBMITTED	Y	
11/18/2023	CONTINUING REVIEW 2 FORM CREATED		
11/15/2023	AMENDMENT 6 FORM APPROVED	Y	Y

11/15/2023	AMENDMENT 6 FORM REVIEWER(S) ASSIGNED		
11/13/2023	AMENDMENT 6 FORM SUBMITTED (CYCLE 1)	Y	
10/26/2023	AMENDMENT 6 FORM PANEL MANAGER REVIEW		
10/25/2023	AMENDMENT 6 FORM SUBMITTED	Y	
08/29/2023	AMENDMENT 6 FORM CREATED		
07/05/2023	AMENDMENT 5 FORM APPROVED	Y	Y
06/30/2023	AMENDMENT 5 FORM REVIEWER(S) ASSIGNED		
06/30/2023	AMENDMENT 5 FORM SUBMITTED	Y	
06/30/2023	AMENDMENT 5 FORM CREATED		
05/03/2023	AMENDMENT 4 FORM APPROVED	Y	Y
05/01/2023	AMENDMENT 4 FORM REVIEWER(S) ASSIGNED		
05/01/2023	AMENDMENT 4 FORM PANEL REASSIGNED		
04/25/2023	AMENDMENT 4 FORM SUBMITTED	Y	
04/24/2023	AMENDMENT 4 FORM CREATED		
03/01/2023	AMENDMENT 3 FORM APPROVED	Y	Y
02/25/2023	AMENDMENT 3 FORM SUBMITTED (CYCLE 1)	Y	
02/14/2023	AMENDMENT 3 FORM REVIEWER(S) ASSIGNED		
02/14/2023	AMENDMENT 3 FORM PANEL REASSIGNED		
02/08/2023	AMENDMENT 3 FORM SUBMITTED	Y	
12/06/2022	AMENDMENT 3 FORM CREATED		
11/30/2022	CONTINUING REVIEW 1 FORM APPROVED	Y	Y

11/29/2022	CONTINUING REVIEW 1 FORM REVIEWER(S) ASSIGNED		
11/29/2022	CONTINUING REVIEW 1 FORM PANEL REASSIGNED		
11/29/2022	CONTINUING REVIEW 1 FORM SUBMITTED	Y	
11/23/2022	CONTINUING REVIEW 1 FORM CREATED		
11/21/2022	AMENDMENT 2 FORM APPROVED	Y	Y
11/07/2022	AMENDMENT 2 FORM REVIEWER(S) ASSIGNED		
11/04/2022	AMENDMENT 2 FORM PANEL REASSIGNED		
11/04/2022	AMENDMENT 2 FORM PANEL REASSIGNED		
11/03/2022	AMENDMENT 2 FORM SUBMITTED	Y	
11/02/2022	AMENDMENT 2 FORM CREATED		
10/21/2022	AMENDMENT 1 FORM APPROVED	Y	Y
10/21/2022	AMENDMENT 1 FORM REVIEWER(S) ASSIGNED		
10/10/2022	AMENDMENT 1 FORM SUBMITTED (CYCLE 1)	Y	
10/06/2022	AMENDMENT 1 FORM CONTINGENT		
09/27/2022	AMENDMENT 1 FORM REVIEWER(S) ASSIGNED		
09/26/2022	AMENDMENT 1 FORM PANEL REASSIGNED		
09/02/2022	AMENDMENT 1 FORM SUBMITTED	Y	
08/16/2022	AMENDMENT 1 FORM CREATED		
03/03/2022	NEW FORM APPROVED	Y	Y
03/02/2022	NEW FORM REVIEWER(S) ASSIGNED		
02/15/2022	NEW FORM SUBMITTED (CYCLE 1)	Y	
12/22/2021	NEW FORM CONTINGENT		

Protocol Title: Effect of knee pain on walking biomechanics

12/13/2021	NEW FORM REVIEWER(S) ASSIGNED	
12/13/2021	NEW FORM PANEL MANAGER REVIEW	
12/09/2021	NEW FORM PANEL ASSIGNED	
12/09/2021	NEW FORM RESUBMITTED	Y
12/07/2021	NEW FORM RETURNED	
12/07/2021	NEW FORM SUBMITTED	Y
12/07/2021	NEW FORM PREREVIEWED	
12/06/2021	NEW FORM PREAPPROVAL	
10/05/2021	NEW FORM CREATED	