

**Informed Consent Document**

Official title: Muscle fatigability and trip-specific fall risk in adults with knee osteoarthritis

NCT number: NCT06229691

Document date: June 20, 2025

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY****Title of Study:** Muscle fatigability and trip-specific fall risk in adults with knee osteoarthritis Principal**Investigator(s):** Jocelyn F. Hafer, Jeremy R. Crenshaw**KEY INFORMATION**

Important aspects of the study you should know about first:

- **Purpose:** The purpose of the study is to determine the relationship between leg muscle fatigability and fall risk in people with knee osteoarthritis.
- **Procedures:** If you choose to participate, you will be asked to complete 2 visits. At visit 1, you will complete questionnaires, perform a 400 meter walk, and practice walking on a treadmill and muscle testing. Between visit 1 and visit 2, you will be given a device to wear around your waist that will record your daily physical activity. At visit 2, you will return the physical activity device and complete balance testing, muscle testing, and a treadmill walking procedure. During these activities, we will place non-invasive markers and electrodes on your body.
- **Duration:** Visit 1 will take approximately 30 minutes and visit 2 will take approximately 2 hours.
- **Risks:** The main risk from this research is that you may trip or become fatigued during balance, muscle tests, and walking.
- **Benefits:** There is no direct benefit to you for participating in this study
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.
- **Costs and Compensation:** If you decide to participate there will be no additional cost to you and you will be compensated \$100 at the completion of the second study visit.
- **Participation:** Taking part or not in this research study is your decision. You can decide to participate and then change your mind at any point.

Please carefully read the entire document. You can ask any questions you may have before deciding if you want to participate.

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you want to participate.

### **PURPOSE OF THE STUDY**

The purpose of the study is to determine the relationship between fatigability and fall risk in people with knee osteoarthritis. Our goal is to develop more effective interventions to enhance mobility and reduce fall risk in older adults with knee osteoarthritis that decrease fatigability.

### **WHO IS BEING ASKED TO PARTICIPATE?**

You will be one of approximately 44 participants in this study.

You are being asked to participate because you fit our participant inclusion criteria for one of the following groups:

- Adults aged 55-70 with no orthopedic conditions
- Adults aged 55-70 with knee osteoarthritis

Individuals with knee osteoarthritis must have:

- Occasional to frequent knee pain
- No more than moderate morning joint stiffness

All individuals will be excluded from participation if they have:

- A history of major cardiovascular disease
- A history of major metabolic disease
- Had a joint injection in the last 3 months
- A lower extremity amputation
- A lower extremity fracture within the last year
- Lower extremity surgery within the last year
- Lower extremity arthroscopy within the last three months
- A need for orthotics or prosthetics to walk
- Neurological pathology which affects movement
- Chronic leg or back pain (except knee pain for those with knee osteoarthritis)
- A need for an assistive device (e.g., braces, cane, walker) to walk for 30 minutes

**PROCEDURES: WHAT WILL YOU BE ASKED TO DO?**

This study will occur in the Kinesiology and Applied Physiology Laboratory at the University of Delaware. This study is expected to take 2 visits and last approximately 2 hours per visit.

Study procedures include:

Visit 1:

- Completing three questionnaires to document your knee health and balance confidence.
- Reporting the number of falls you have experienced in the last year.
- Wearing athletic clothing: shorts, t-shirt, sneakers. If you do not have athletic clothing, clean clothing in your size will be provided.
- Completing 400-meter walk at a comfortable speed.
- Practicing muscle power and treadmill walking tests.
- Performing practice muscle power testing which will measure the strength of your leg muscles by offering three different resistance.

Between visit 1 and visit 2:

- Wearing a waist-worn accelerometer until the next visit (5-7days).
- Completing a supplementary physical activity log.

Visit 2:

- Completing a questionnaire to document your knee health.
- Complete a Flanker Test to assess cognitive fatigue at the beginning and end of the visit.
- Wearing athletic clothing: shorts, t-shirt, sneakers. If you do not have athletic clothing, clean clothing in your size will be provided.
- Having a study researcher place small reflective plastic markers on your body using adhesive tape and elastic wraps. These markers will be placed on your entire body.
- Having a study researcher also place inertial measurement units (IMUs) and electromyography (EMG) electrodes on your lower extremity and torso using adhesive tape, elastic wrap or Velcro straps.
- Completing a balance test which involves a push and release test. You will stand on the middle line of the treadmill and lean on a researcher, they will then release you and you must catch yourself by taking a single step. Participants will perform this three times.

- Performing muscle power testing we will measure the strength of your leg muscles by offering three different resistance Participants will perform three sets of 5 times for each condition.
- Walking on a treadmill in the laboratory. You may complete the 30-minute treadmill walk at multiple speeds and the speed may change during the trial.
- You will follow the same balance and muscle tests protocol as you did before the treadmill walking.

This study does not include any clinical procedures and as such, there are no known alternatives available to you other than not taking part in this study.

#### **WHAT ARE POSSIBLE RISKS AND DISCOMFORTS?**

Possible risks of participating in this research study include:

- Tripping or falling while walking or completing a balance test
- Fatigue from walking
- Muscle soreness after muscle power testing
- Mild discomfort when removing adhesive tape or irritation from tape and wraps
- Occasionally, some subjects feel nervous during balance testing

Tripping/falling and fatigue risks are no greater than if you were walking in typical life. These risks will be minimized by keeping all walking areas clear of obstacles. Research staff will be near you at all times to maintain safety. While on the treadmill, you will be equipped with a safety harness system attached to an overhead rail to stop a fall, should any occur, prior to your knees or hands contacting the treadmill or floor. Researchers will also verify that wraps and tape are comfortable and make sure that discomfort is minimized.

#### **WHAT ARE POTENTIAL BENEFITS FROM THE STUDY?**

You will not benefit directly from taking part in this research. However, the knowledge gained from this study may contribute to a better understanding of fall risk in people with knee osteoarthritis, especially in terms of fatigability. We hope this information will help us develop mobility-improving rehabilitation training for older adults with knee osteoarthritis.

#### **NEW FINDINGS THAT COULD AFFECT YOUR PARTICIPATION**

During the course of this study, we may learn new important information. This may include information that could cause you to change your mind about participating in the study. If any new important information becomes available while you are a participant we will let you know.

#### **CONFIDENTIALITY: WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?**

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used.

- To minimize the risks to confidentiality you will be identified using a coded subject ID on all research data, and only Drs. Hafer and Crenshaw will have access to a key linking your name to your research data. Any records with your name will be stored separately from research data in a locked cabinet or on a password-protected computer. At the end of the study, all identifying information and the key linking your name to your data will be destroyed.
- Research results may be presented at conferences or in published manuscripts. In all cases, no information identifying you as a participant in this research will be given.

We will keep your study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as child abuse, or intent to hurt yourself or others.

If required, your records may be inspected by authorized personnel in the following groups and agencies: The University of Delaware Institutional Review Board.

#### **USE OF DATA COLLECTED FROM YOU IN FUTURE RESEARCH:**

Identifiers about you might be removed from the identifiable private information and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

#### **COSTS AND COMPENSATION**

There are no costs associated with your participation in this study.

You will receive \$100 upon the completion of visit 2.

#### **WHAT IF YOU ARE INJURED DURING PARTICIPATION IN THE STUDY?**

If you are injured during your participation in the study, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of a thirdparty payer (for example, your health insurance). By signing this document, you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

#### **DO YOU HAVE TO TAKE PART IN THIS STUDY?**

Taking part in this research study is your decision. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide later not to participate, or if you decide to stop taking part in the research, there will be no penalty or loss of benefits to which you are otherwise entitled.

Your decision to stop participation, or not to participate, will not influence current or future relationships with the University of Delaware.

The investigator reserves the right to remove you from the study without your consent if he/she feels it is in the best interest. This may occur if the investigator feels that you do not understand the study procedures, that you are behaving in an unsafe manner, or if you experience significant fatigue or pain.

### **INSTITUTIONAL REVIEW BOARD**

This research study has been reviewed and approved by the University of Delaware Institutional Review Board (UD IRB), which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. If you have any questions or concerns about your rights as a research participant, you may contact the UD IRB at [hsrb-research@udel.edu](mailto:hsrb-research@udel.edu) or (302) 831-2137.

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### **CONTACT INFORMATION**

If you have any questions about the purpose, procedures, or any other issues related to this research study you may contact the Principal Investigator, Jocelyn Hafer, PhD at (302) 831-3471 or [jfhafer@udel.edu](mailto:jfhafer@udel.edu).

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### **CONSENT TO PARTICIPATE IN THE RESEARCH STUDY:**

I have read and understood the information in this form and I agree to participate in the study. I am 18 years of age or older. I have been given the opportunity to ask any questions I had and those questions have been answered to my satisfaction. I understand that I will be given a copy of this form for my records.

**OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES:**

Do we have your permission to contact you regarding participation in future studies? If you agree to being contacted in the future, we will keep your contact information. Please write your initials next to your preferred choice.

_____ Printed Name of Participant (PRINTED NAME)	_____ Signature of Participant (SIGNATURE)	_____ Date
_____ Person Obtaining Consent (PRINTED NAME)	_____ Person Obtaining Consent (SIGNATURE)	_____ Date
<div style="text-align: center;">_____ YES</div>		
<div style="text-align: center;">_____ NO</div>		

**OPTIONAL CONSENT FOR ADDITIONAL USES OF IDENTIFIABLE VIDEO RECORDINGS/PHOTOGRAPHS**

I voluntarily give my permission to the researchers in this study to use videos and photographs of me collected as part of this research study for publications, presentations, and/or educational purposes. I understand that no identifying information beyond that contained in the video recording will be provided to educational/scientific audiences; however my facial features may be seen.

_____ (Printed Name of Participant OR Parent/Guardian)	_____ (Signature)	_____ (Date)
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