UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Mi-SPA: Michigan Split-belt Adaptation Paradigm to Improve Knee Loading After Anterior Cruciate Ligament Reconstruction

Company or agency sponsoring the study: No agency is sponsoring this study at the current time.

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Riann Palmieri-Smith, Ph.D., ATC, School of Kinesiology and Department of Orthopaedic Surgery, University of Michigan

Study Coordinator: Alexa Johnson, Ph.D., School of Kinesiology, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose: Knee and limb underloading (i.e., less force is transmitted up the injured leg) is very common after anterior cruciate ligament (ACL) reconstruction and fails to resolve with the standard of care rehabilitation. This underloading behavior is clinically concerning it affects patient function, has been linked to risk for re-injury, and may be involved in causing knee osteoarthritis that affects upwards of 50% of patients who undergo an ACL reconstruction. The purpose of this study is to test whether split-belt treadmill training can increase knee and limb loading after ACL reconstruction.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

People between the ages of 14-45 who have undergone ACL-reconstruction can participate. If interested, you need to be willing to participate in testing and/or training sessions as outlined in this document.

You may NOT be in the study if you:
1) have suffered a previous ACL injury;
2) have undergone previous major surgery to either leg knee;
3) have a history of recent significant knee injury (other than ACL) or lower-extremity fracture;
4) underwent a multi-ligamentous reconstruction at the time of your ACL surgery (i.e., the doctor reconstructed more than one ligament at the time of your ACL surgery)
4) are pregnant or plan to become pregnant;

Before you sign this consent form and we bring you in for testing, we will ask you a series of questions that helps us to determine whether you meet these criteria. We will also check your medical record to ensure you meet some of these criteria.

3.2 How many people are expected to take part in this study?
We will enroll up to 100 people in the current study, which has three parts. Part one of this study, will enroll up approximately 27 participants, part 2 will enroll approximately 38 participants, and part three will enroll about 9 participants. We may need to enroll more subjects in each part if a subject chooses not to continue with the study or data are incomplete, etc.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments and report any adverse reactions you may have during the study.

For all parts of the study: When you report to the lab, you will be asked to wear shorts and running/tennis shoes during testing. We will ask males to not wear a shirt and females to wear a sports bra. This allows for our cameras to see the markers that we will apply to your skin and is necessary so we can get accurate measurements. After answering some questions about your medical/ACL history, you will be asked to walk at your normal pace overground a few times so we can determine how fast you like to walk. After this, we will put some round balls on your skin using tape and wraps so that we can track how you walk on a treadmill. The rounds balls are followed by specialized cameras in the lab as you move and allow us to see what positions your legs and body are in. We may also apply sensors to the skin on your legs, called EMG sensors, that allow us to measure muscle activity. These sensors will not hurt you in anyway (i.e., no shocks or energy will be applied to your body) and will simply measure how your muscles are acting. You will also be asked to complete a few questionnaires about your knees and physical activity level at some point during study testing. We will also ask questions about the walking speeds throughout all of the studies to see if they were difficult for your or not.

Part 1: If you are asked to participate in first part of this study you will need to come to the ORB laboratory located in MedSport Domino's Farms on two separate occasions. During each session you will walk on the split-belt treadmill for about an hour at a variety of speeds. In one session, we will train your ACL leg on a treadmill and in the other session we will training your Non-ACL/uninjured leg. Training will involve you walking on a split-belt treadmill (i.e., a treadmill that has two belts one under each leg, which can move at the same or different speeds). On the day we are training your ACL leg, we will adjust the speed of the treadmill belt under your ACL leg, while your uninjured leg will walk at your normal pace. On the day we are training your Non-ACL leg, we will adjust the speed of the treadmill belt under your Non-ACL leg, while your ACL leg will walk at your normal pace. We will have you walk at each speed for about 5 minutes and between each speed change will walk with both treadmill belts moving at the same speed for a couple minutes. At the end of each session, we will remove all markers and electrodes placed on your body. When done with testing for this part of the study, you may be asked if you are willing to comeback and participate in other portions of this study at a later time. It is also possible that unexpected issues could arise with equipment, etc. and you would be asked to come back to the lab again for this portion of the study (this is unlikely, but could occur).

Part 2: If you are asked to participate in the second part of this study, you will be randomized to one of two groups (i.e., like flipping a coin). One group will train their ACL leg and the other group will train their Non-ACL leg. To participate, all volunteers will need to come to the ORB laboratory located in MedSport Domino's Farms on two separate occasions. During each session you will walk on the split-belt treadmill for about 40 minutes. In one session, the belts on the split-belt treadmill will be set to move at the same speed and in the

other session the belts on the split-belt treadmill will be set to move at different speeds. At the end of each session, we will remove all markers and electrodes placed on your body. When done with testing for this part of the study, you may be asked if you are willing to comeback and participate in other portions of this study at a later time. It is also possible that unexpected issues could arise with equipment, etc. and you would be asked to come back to the lab again for this portion of the study (this is unlikely, but could occur).

Part 3: If you are asked to participate in the third part of this study, you will be randomized to one of three groups (i.e., one in three chance). Two of the three groups will have their ACL leg trained on the split-belt treadmill and the third groups will have the Non-ACL leg trained. If you are assigned to a group where we are training your ACL leg, we will adjust the speed of the treadmill belt under your ACL leg, while your uninjured leg will walk at your normal pace. If you are assigned to a group where we are training your Non-ACL leg, we will adjust the speed of the treadmill belt under your Non-ACL leg, while your ACL leg will walk at your normal pace. Participants in all 3 groups will do training 2 times per week for 6 weeks with each training session lasting about 1 hour. These training sessions will be scheduled at a time convenient for you and can be scheduled in conjunction with your normal physical therapy appointments to limit travel back and forth to domino's farms. Participants will also be asked to come to the lab for 3 testing visits (before starting the treadmill training, mid-way through the treadmill training (e.g., 3 weeks after the start of training), and after the training is over). During the testing sessions, we will put markers on your skin like we do for the training sessions and you will walk on the treadmill with the belts moving at the same speeds and you will also be asked to walk overground.

4.2 How much of my time will be needed to take part in this study?
For volunteers participating in studies 1 and 2 the time commitment is approximately 4-5 hours (2 to 2.5 hours for each session) over 1-3 weeks. For volunteers participating in study three, the study will be complete after 8 weeks and the total time commitment is about 20 hours (3 testing sessions each last 2-2.5 hours and 12 training sessions lasting about 1 hour).

4.3 When will my participation in the study be over?
For volunteers participating in part 1 or part 2 of this study, participation will take place over the course of 1-3 weeks. When you finish both data collections associated with either of the studies, your participation will be over. For those participating in part 3, your participation will be over after you complete all 12 training sessions and all 3 testing sessions. It is expected that those participating in part 3 will be in the study for about 8 weeks. It is expected that all 3 studies will take place over the course of 3 years.

4.4 What will happen with my information used in this study?
With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

- **Allergic reactions (Infrequent):** You may experience allergic reactions from the application of electrode paste and adhesive tapes necessary for attaching electrodes or markers. Similarly you could have a reaction to the ultrasound gel. We will use hypoallergenic tapes to minimize

allergic reactions. If redness or excessive itching occurs, the area will be monitored closely by study staff and testing will be ended at their discretion or in accordance with your wishes.

- **Skin irritation (infrequent):** You may experience some skin irritation from the tapes and sensors attached to your body, especially when removing them. This should be temporary and should usually go away by applying skin lotion. You may decide to shave your legs before the study visit.
- **Muscle or Joint Discomfort and Swelling (Infrequent):** During or following the experiment, you may feel temporary or persistent muscle aching or joint pain, swelling, or general fatigue. We will provide appropriate rest breaks during the experiment. The level of soreness should not be greater than what would be experienced following a regular exercise session.
- **Muscle Strain, Ligament Sprain, or patellar fracture (Rare):** There is a small risk of injury during the walking.
- **Breach of Confidentiality (Rare):** Confidentiality refers to the researchers' agreement to handle, store, and share research data to ensure information about you is not improperly revealed. We will only share data among the study team members. All data that is associated with you will be identified with a study ID number and only the study team will have the file that links you with your study ID. Once the study is complete, we will destroy the file that links you to your data. All data will be transferred and stored on secure devices and servers. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.
- **Unforeseeable Risks:** As with any research study, there may be additional risks that are unknown or unexpected. If you have any questions or are unsure about anything outlined below please do not hesitate to ask the study team.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.** If you were to get hurt or become sick during this study the researchers would provide basic first aid. Additionally, depending on the extent of the injury or illness you may be removed from the study.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. For those volunteers participating in study 3, you may see sustained improvements in knee and limb loading which may benefit long-term knee joint health.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
You do not have to participate in this research study. You will still receive standard physical therapy after your surgery whether you are in the study or not. There may also be other ways of treating your condition, including other experimental therapies. Your doctor or surgeon can tell you more about these other treatments, their risks and their possible benefits. You should have this discussion about the risks and benefits or other alternatives prior to making your decision about whether or not you wish to take part in this research study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished? No harm will come to you if you decide to leave the study early.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
Subjects in all three study parts will be paid $15/hour for your participation in this study. If you leave the study early for any reason, you will be paid for the time you spent participating in the study.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

- In any publications that result from this research report, neither your name, nor any information from which you may be identified will be published without your consent.
- Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.
- Personal identifiers will be removed from the data before we share any of this information with anyone else.
- Only the research investigators of this study will have access to the list that connects identifying information with your information. This will be kept in a locked cabinet in the study teams offices or labs.

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

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment

- Billing information
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly
-

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission will not expire unless you cancel it.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Riann Palmieri-Smith, Ph.D., ATC
Mailing Address: 830 N. University Avenue, Ann Arbor, MI 48109
Telephone: 734-615-3154

Study Coordinator: Alexa Johnson, Ph.D.
Mailing Address: 24 Frank Lloyd Wright Dr. Suite 1000, Lobby A
Telephone: 734-615-1297

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This signed and dated "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent/Assent to video/audio recording/photography solely for purposes of this research

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you can still take part in the study. Please note that the cameras around the research lab do not record physical images of your person. If we are going to record identifiable videos of you or take pictures you will be notified prior to starting any testing or training.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name: _____

Signature: _____

Sig-E

Legally Authorized Representative or Parent Permission

Subject Name:

_____

Parent/Legally Authorized Representative:

Printed Legal Name:

_____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If "Other," explain: _____

Reason subject is unable to consent: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____