

## **Consent to be Part of a Research Study**

Title of the Project: Validation of a Wearable Device to Measure Ground Reaction Force  
Principal Investigator: Amanda Esquivel, Ph.D., University of Michigan Dearborn

### **Invitation to be Part of a Research Study**

You are invited to participate in a research study. In order to participate, you must be an adult that currently plays basketball or soccer, have an absence of lower extremity pain, and a BMI<29. Taking part in this research project is voluntary.

### **Important Information about the Research Study**

Things you should know:

- The purpose of the study is to determine whether wearable devices can measure leg motion – particularly whether they can estimate how much force you are landing with. If you choose to participate, you will be asked to wear a small sensing device above and below your knee, along with small markers stuck to your hip, knee, and ankles. While wearing these, you will complete a set of nine athletic movements described in further detail below. This will take approximately 40-60 minutes of your time.
- Risks or discomforts from this research include the very small risk that you could injure yourself when you jump or run and the very slight risk that data we collect could be stolen.
- The study may not directly benefit you, but others may benefit because developing a wearable device to monitor knee motion could help prevent ACL injuries in athletes.
- Taking part in this research project is voluntary. You don't have to participate and you can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

### **What is the study about and why are we doing it?**

The purpose of the study is to determine whether wearable devices can measure leg motion – particularly whether they can estimate how much force you are landing with.

### **What will happen if you take part in this study?**

If you agree to take part in this study, you will be asked to allow a member of the research team to put a small sensing device above and below your knee. We will then stick small markers to your hip, knee and ankle. We will ask you to complete the following activities:

	Movement	Description
1	Jog with pivot	Participant jogs a few steps and pushes off of dominant leg to turn body towards the opposite side.

2	Extension Leap	Participant pushes off of dominant leg while fully extending the non-dominant leg to land on force plate more than two comfortable step lengths away.
3	Sidestep Cut	Subject accelerates toward the direction opposite of the planted leg
4	Crossover Cut	Participant crosses one leg over the planted leg and accelerates in the same direction of the push off leg
5	Dominant Shooting	Non-dominant foot takes a firm step onto force plate to support the dominant leg swing through a “shooting” motion.
6	Jump – land on one foot	Subject stands with feet together, jumps her maximum height and lands on one foot.
7	Low Jump	Subject stands with feet together, jumps what he/she perceives to be a low height and lands on both feet
8	High Jump	Subject stands with feet together, jumps him/her maximum height and lands on both feet
9	Mid Jump	Subject stands with feet together, jumps a height between that of the low and high jump and lands on both feet

These activities are similar to those performed as part of regular athletic activity or when exercising. Activity #5 will be for soccer players only. We will measure what is happening with your leg using these markers, special video cameras that will be set up around the room and software that can track these markers. We will compare data we collect from the camera system to data from the device that is above and below your knee. The video cameras will record your movements but these recordings do not include your face. We expect that this will take 40-60 minutes of your time. You can first practice this motion until you are comfortable.

#### **How could you benefit from this study?**

Although you will not directly benefit from being in this study, others might benefit because developing a wearable device to monitor knee motion could help prevent ACL injuries in athletes.

#### **What risks might result from being in this study?**

There are some risks you might experience from being in this study. There is a very small risk that you could injure yourself when you jump or run. We will minimize this risk by letting you practice several times slowly until you feel comfortable doing this. If there are any movements that make you feel nervous, just let us know and we will skip those. Should you become injured, campus security will be called to provide assistance. There is also a very slight risk that data that we collect could be stolen. We will minimize this risk by only storing your data on a password protected computer.

### **How will we protect your information?**

I plan to publish the results of this study. To protect your privacy, I will not include any information that could directly identify you.

I will protect the confidentiality of your research records by not including any information that would identify you. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project. I will be recording your movements. Any pictures used for publication will first be altered so that no one can see your face. Only members of the research team will have access to your research files and data. Digital files will be encrypted to protect the confidentiality of the data.

It is possible that other people may need to see the information we collect about you. These people work for the University of Michigan and government offices that are responsible for making sure the research is done safely and properly.

### **What will happen to the information we collect about you after the study is over?**

We will keep your research data to use until we are finished collecting and analyzing all data for this study. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you.

### **Your Participation in this Study is Voluntary**

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, we will stop collecting your data and delete it from the files.

### **Contact Information for the Study Team and Questions about the Research**

If you have questions about this research, including questions about scheduling, you may contact **Dr. Esquivel** at **aoe@umich.edu** or call her at **313-593-4320**.

### **Contact Information for Questions about Your Rights as a Research Participant**

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan  
Health Sciences and Behavioral Sciences Institutional Review Board  
2800 Plymouth Road  
Building 520, Room 1169  
Ann Arbor, MI 48109-2800

Phone: (734) 936-0933 or toll free, (866) 936-0933

Email: [irbhsbs@umich.edu](mailto:irbhsbs@umich.edu)

### Your Consent

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study.*

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Printed Subject Name

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Signature

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Date