INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Title of Project: Novel Flexible Sensors in Functional Fabrics for Performance Monitoring

Principal Investigator(s): Erik Thostenson and Jill Higginson

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.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to validate a new class of wearable, flexible sensors (Smart Sleeve, Smart Footwear, and SmartBoot 2.0). These sensors will measure joint motions and forces during activities of daily living. If validated these garments would allow us to measure these variables outside of the laboratory.

You will be one of 60 participants in this study.

WHY ARE YOU BEING ASKED TO PARTICIPATE?

You are being asked to participate because you are a healthy adult between the ages of 18 – 80 and are able to walk safely on a treadmill. You will not be able to participate in this study if you are currently pregnant, have a muscle, bone, or skin condition. You will be asked to complete a physical activities readiness questionnaire (PAR-Q) and will be excluded if your answers suggest you should not physically exert yourself.

WHAT WILL YOU BE ASKED TO DO?

As part of this study you may be asked to test one or more of the following sensors: SmartSleeve, SmartFootwear or SmartBoot 2.0. In most cases, you will only be asked to wear one sensor at a time, however it is possible that a sleeve, footwear, and/or boot might be worn simultaneously

SmartSleeve measures extension/stretching as well as curvature sensing of the elbow and SmartFootwear measures fabric-based force sensing of the foot. The SmartBoot 2.0 measures the reaction forces during walking and step count. You will come in for one data collection session at STAR campus which should not exceed 1 hour.

Subjects testing the Smart Sleeve will complete a series of upper extremity tasks while wearing the Smart Sleeve positioned over the elbow. During data collection the you will perform the following common arm motions: standing in a neutral posture, raise hand to face and return, raise hand to lower back and return, raise hand to top of head and return, lift object over head with both arms and return, and move through full range of elbow motion (flexion/extension, pronation/supination) with shoulder in a neutral posture. Motion

Participant's Initials _____

capture of the upper extremities will be collected by placing roughly 30 small plastic reflective markers on the trunk and arms and will measure upper extremity joint angles.

Subjects testing the Smart Footwear will complete the following tasks with the footwear positioned on the foot: rise from a seated position – stand for 10 seconds – return to seated position (repeated 5 times), walk at a slower than normal (0.75 m/s) speed (30 sec) walk at average walking speed (~1.25m/s) on treadmill (30 seconds), slow jog (~1.5-2m/s) on a treadmill (30 seconds). Subjects will be asked to walk along the hallways and up and down the stairs in the STAR Health Science Complex building. Peak horizontal and vertical ground reaction forces will be compared between the Smart Footwear and the treadmill force plates.

Subjects testing the SmartBoot 2.0 will be asked to complete a series of walking tasks on a treadmill for four different conditions wearing the boot instead of a shoe on one side. The conditions are as follows: normal walking, walking with SmartBoot 2.0 alone, SmartBoot 2.0 with a compressible sole, and SmartBoot 2.0 with a heel wedge. Each condition will be tested for 3 trials at 1 minute per trial with a 1 minute break between trials for a total of 5 minutes per condition. Peak heel strike force, peak toe-off force, and step count will be compared between the SmartBoot 2.0 and the treadmill force plates. Motion capture data will be collected by placing roughly 30 small plastic reflective markers on the trunk and legs to measure joint angles and will be analyzed for possible changes in walking biomechanics.

After each trial, you will be asked to respond to a survey.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The possible risks associated with this study will include falling, fatigue, and joint soreness in your leg. Injuries such as muscle strains and tears are possible but unlikely. You will wear a safety harness during the treadmill testing that will prevent you from falling to the ground should you lose your balance. At any time during testing, if needed, the experimenter can push a safety switch on the treadmill that will stop the treadmill belt immediately. Mild skin irritation due to the sleeve, Footwear, or SmartBoot 2.0 is also possible. The boot of the SmartBoot 2.0 is a typical orthopaedic boot that is prescribed if someone has an ankle or foot injury. Wedges are also commonly used in the boot to modify loading on the Achilles tendon. It may cause temporary asymmetry in walking patterns.

WHAT IF YOU ARE INJURED DURING YOUR PARTICIPATION IN THE STUDY?

If you are injured during research procedures, 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 your third-party 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.

WHAT ARE THE POTENTIAL BENEFITS?

There is no direct benefit to you however potential future benefits include possible development of treatments for people with movement disorders.

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HOW WILL CONFIDENTIALITY BE MAINTAINED? WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

Your personal information will be kept confidential. A Patient Identification Number (PID) will be assigned to each subject. Any paper files with personal data will be placed in locked cabinets and electronic files will be password-protected. Data will be de-identified and post-processed for descriptive statistics describing group behavior and may be kept indefinitely. Results may be shared in presentations, conference abstracts, and journal publications. A musculoskeletal model will be scaled to fit motion capture data for each subject. Joint motion and forces will be calculated using available software. Outcome variables will be compared for statistical differences.

The confidentiality of your records will be protected to the extent permitted by law. Your research records may be viewed by the University of Delaware Institutional Review Board, which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. Records relating to this research will be kept for at least three years after the research study has been completed.

WILL THERE BE ANY COSTS TO YOU FOR PARTICIPATING IN THIS RESEARCH?

There are no costs to you.

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATION?

There is no compensation.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is entirely voluntary. 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 not to participate or if you decide to stop taking part in the research at a later date, 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.

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WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Erik Thostenson at 302-831-8789 or thosten@udel.edu.

If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at hsrb-research@udel.edu or (302) 831-2137.

Your signature on this form means that: 1) you are at least 18 years old; 2) you have read and understand the information given in this form; 3) you have asked any questions you have about the research and those questions have been answered to your satisfaction; 4) you accept the terms in the form and volunteer to participate in the study. You will be given a copy of this form to keep.

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Printed Name of Participant	Signature of Participant	Date

_____	_____	_____
Person Obtaining Consent (PRINTED NAME)	Person Obtaining Consent (SIGNATURE)	Date

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OPTIONAL CONSENT FOR ADDITIONAL USES OF VIDEO RECORDINGS/PHOTOGRAPHS

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

_____	_____
Signature of Participant	Date

Participant's Initials _____

Participant's Initials _____