Informed Consent Agreement for Participation in a Research Study

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Contact Information:
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Email: [Redacted]

Title of Research Study: Development of a Customizable Bio-Mechanical Actuated Knee Joint for Exoskeleton

Introduction
You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study:
Human knees tend extend as they are bent at a different rate between people. This study aims to look at the flexion and extension patterns in different people using a motion capture system and a Magnetic Resonance Imager (MRI).

Procedures to be followed:
This study will specifically look at the shape and internal structure of your knee and mid-leg skeletal system. The study will comprise of two separate days.

1. On the first day, you will go over this consent form. You will also fill an MRI screening form, which asks about your past medical history to determine if there are contraindications for your participation in the study. All medical history data will be kept confidential and will **NOT** be publicized with the results of the study.
2. After the onboarding process (step 1), you will go through the first part of the study: the motion capture session. You will have special dots placed on you, and a system will determine and track the position of those dots.
3. You will be asked to come back on a later day (roughly in a week) and a new customized biomechanical joint will be manufactured in the meantime.
4. On the day of the MRI, you will once again go over your MRI screening form with an MRI technician to ensure your medical history has not changed. You will also be given a chance to change into clean scrubs (provided by PracticePoint).
5. You will have an MRI safe biomechanical joint attached to you before you enter the MRI. The MR imaging session will consist of approximately 3 imaging sequences of your knee at approximately 3 different angles. Each scan should take

roughly 15 minutes, with a short setup period beforehand. Pictures of your knee at each angle will also be taken before you enter the MRI system.

Motion Capture Study time to complete: **roughly 1 hour**
Magnetic Resonance Imaging (MRI) Procedure time to complete: **roughly 1 hour**

All image data will be anonymized, and your name will be omitted from all published material. A key will be kept ensuring continuity between the first and second scan. To read more about the study's privacy policy, please see the section titled *Record Keeping and Confidentiality* below.

This study involves a magnetic resonance imaging (MRI) scan. MRI is a technique for taking images of the body's internal structures. It uses a magnetic field and radio waves – no ionizing radiation is used. We will take you to the MRI imaging suite at WPI's PracticePoint research facility and ask you a series of safety questions before we bring you into the MRI room. Some of these questions might be repetitive but it is important that we make sure it is safe for you to have an MRI scan.

Because the scanner contains an extremely strong magnet you will be asked to remove all metal objects on you and place them in a provided locker. This includes items including watches, rings, necklaces, bracelets, earrings, and other body piercings, belts, loose change, wallet (with credit cards), items of clothing containing magnetic materials (for example, under wire bras, certain types of zippers), and shoes. It is recommended that you leave valuables and jewelry at home. We will ask you to change into a provided hospital gown or scrubs in our screening/changing room before you go into the scanning room. Your clothing and personal items will be locked up in a safe place until the session is completed.

You will spend approximately 45 minutes in an MRI scanner, which looks like a large cylinder with a tube running down the center. You will be asked to lie down on your back on a foam padded table. An imaging coil will be placed on or around the part of the body we are scanning. The table slides inside the "hole" of the scanner. Soft foam sponges may be placed on both sides of your head or next to various parts of your body to help keep you still. A headset with microphone allows you to hear and talk to the technician operating the scanner at all times.

During the scanning procedure, you will hear a number of different sounds. These sounds, which can be loud, are part of the normal operation of the scanner. These noises vary with the particular scan being performed, and include sounds like a hammer hitting a piece of wood, repetitive buzzing noises, and long series of loud beeps. Some scans are silent. These sounds, or combinations of them, will then be repeated several times, depending upon the specific scan sequence being used. The sounds you hear during the scanning session will not harm your hearing, but you will be given a pair of earplugs to wear for your comfort. Even with these earplugs in you will always be able to hear the technician because they do

not block all sound. You are free to talk during the preparation time and during breaks, but you should not talk during the actual scanning process. During these sessions, you should try to remain as still as possible.

The entire duration that you will be in the scanner is not expected to be longer than 60 minutes. When the session is over the technician will move you out of the scanner and assist you from the table. You will then exit the scanner room, return to the screening/changing room to change back into your clothes and retrieve your belongings.

The MR images are stored digitally. Thousands of patients across the country safely undergo MR imaging in radiology departments every day. The MR imaging itself is not experimental; rather, it is well known to be safe.

Risks to study participants:
Magnetic Resonance (MR) imaging does not use ionizing radiation like an X-ray. Instead, it uses strong magnetic fields and radio-frequency waves to collect the images and data. There are no known serious health hazards or risks associated with these techniques for most people. However, significant risks may exist for people with:

- Cardiac pacemakers
- Aneurysm clips (in your brain) and other vascular stents (tubes in your veins), filters, clips, or other devices that have been surgically put in you for any reason.
- Prosthetic heart valves (a mechanical device that helps your heart pump blood)
- Other prostheses (a piece of equipment that replaces a missing part of the body)
- Neuro-stimulator devices (a piece of equipment that activates nerves)
- Implanted infusion pumps (a device that stays in your body and helps give you medicine)
- Cochlear (ear) implants (a device used to help you hear)
- Ocular (eye) implants (a device put in your eye to help you see)
- Metal fragments or pieces in eyes
- Contact with metal filings (people who are sheet metal workers, welders, or others could have this contact)
- Any surgeries where something metal was put in you
- Certain tattoos (please tell the study doctor if you have a tattoo so that we can make sure it is safe)
- Certain intrauterine contraception devices (IUD's)

You will be asked whether you have such devices and if so, you will not be able to participate in this study. Significant risks also can arise if certain types of metal objects are brought into the scanning area, as they can become hazardous projectiles. These types of items are not permitted in the scanning area, a locker will be provided for you to keep your belongings secure during the study. It is important to remember that ***the Magnet is***

ALWAYS On even when a scan is not taking place. The exams are painless, and except for the pulsating sounds, you will not be aware that MR scanning is taking place.

This study will be conducted in an MR scanner which has been approved by the FDA for clinical and research studies. Although there are no known significant health risks from these scans, there could be adverse effects that are delayed or very mild, such that they have not yet been recognized. Most people experience no ill effects from the large magnetic field, but some people do report claustrophobia (fear of being in small spaces), dizziness, mild nausea, headaches, a metallic taste in their mouth, double vision or sensation of flashing lights. These symptoms, if present, disappear shortly after leaving the MR machine. If you experience discomfort from being in the scanner, you should notify the examiner immediately and you will be removed from the scanner. You will be provided a squeeze ball that sounds an alarm at the operator's console for this purpose. You should also note you will be asked to remain as still as possible during the scanning session. Remaining motionless can result in discomfort.

You may feel cramped inside the scanner. The technologist will be able to hear you at all times and you are free to end the procedure at any time.

In rare cases, a very slight, uncomfortable tingling of the back due to the rapid switching of the magnetic field has been reported during certain types of scans. In case you have such a sensation, you are asked to report this immediately, so the scan can be changed to avoid this. Although these precautions will avoid all known risks associated with MR, this procedure may involve risks to you that are currently unforeseeable.

Benefits to research participants and others:
There may be no benefit to being in this study. The images in this study are not being collected for the purpose of diagnosing a medical condition. The images will not be reviewed by a medical professional. If you feel that you have a medical condition requiring an MRI scan, you should schedule a visit with your primary care physician for a referral to a clinical imaging facility. In the unlikely event that a finding warranting further consultation with a physician is identified in your scans, you may be contacted by the study personnel. Any additional medical work or consultation needed as a result of this study will be the responsibility of the participant.

Record keeping and confidentiality:
All images will be labeled with an anonymized subject number. Images will be transferred off the scanner console at the end of each imagining session. Only anonymized images which do not reveal any personally identifying features will be used in publications or uploaded to open-source medical image repositories.

MR screening forms will be handled carefully by research staff. Once reviewed, these forms will be stored in a locked drawer inside of a locked room. They will only be reviewed by the research staff, the PracticePoint designated MR safety supervisor, and consulting medical professionals when required.

A key will be kept matching anonymized subject numbers and personally identifiable information – including contact information - in order to match data between the first and second scan. This key will be encrypted and password-protected and will be deleted at the end of the study. The key will not be shared with anyone except the investigators.

Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or it's designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you.

Compensation or treatment in the event of injury:
If you are injured while participating in this study, seek treatment and contact the study principal investigator as soon as you are able.

WPI does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, you should seek treatment as you would normally. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

Cost/Payment:
Participating in this study will NOT require a payment, co-payment, or insurance charge. There will be no cost to you from being in this research study other than the cost of your transportation to WPI.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact:

Primary Investigator: Alex Tacescu
Tel. : (559) 301-6222
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Tel.: (508) 831-6699
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Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of

other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit.

There are no risks to dropping out of this study.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____ Date: _____

Study Participant Signature

_____

Study Participant Name (Please print)

_____ Date: _____

Signature of Person who explained this study

_____

Person who explained this study (Please Print)

Additional clauses to add to Consent Agreements, as appropriate:

Significant new findings or information, developed during the course of the research, may alter the subject's willingness to participate in the study. Any such findings will be promptly communicated to all research participants.

Should a participant wish to withdraw from the study after it has begun, the following procedures should be followed:

1. Please email the primary investigator as soon as possible. Make sure you get a confirmation from them. You may contact them at the following email: actacescu@wpi.edu

There are no consequences from withdrawing from this study.

Special Exceptions: Under certain circumstances**,** an IRB may approve a consent procedure which differs from some of the elements of informed consent set forth above. Before doing so, however, the IRB must make findings regarding the research justification for different procedures (i.e. a waiver of some of the informed consent requirements must be necessary for the research is to be "practicably carried out.") The IRB must also find that the research involves "no more than minimal risk to the subjects." Other requirements are found at 45 C.F.R. §46.116.