Department of Veterans Affairs	Informed Consent Form	COMIRB APPROVED For Use 27-Apr-2020
Valid Through: Per COMIRB	**R&D Stamp:** VA R&D	**COMIRB Approval Stamp/Date:**
Version Date: 04/27/2020		

Subject Name: _____ **Date:** _____

Title of Study: Optimizing Prosthetic and Bicycle Fit for Veterans with Transtibial Amputations

Principal Investigator: Alena Grabowski **VAMC:** 554

VA Investigator: Alena Grabowski **COMIRB#** 18-2783

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

We do not yet know how different prosthetic and bicycle configurations for the affected leg influence performance in people with a lower extremity amputation. These configurations include pedal attachment position beneath the fore-foot versus the pylon, the pylon length, and the crank arm length. Our primary objective is to optimize prosthetic and bicycle fit for people with lower extremity amputation during bicycling.

This study plans to learn more about how different prosthetic and bicycle configurations affect bicycling performance.

You are being asked to be in this research study because you:

1. are between 18-55 years old
2. have a unilateral below the knee amputation and are at least 1 year post-amputation.
3. have at least a K3 Medicare Functional Classification Level, which is defined as a person who has the ability or potential for ambulation with variable cadence. A person at K3 MFCL is a typical community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic or exercise activity that demands prosthetic use beyond simple locomotion.
5. have no known cardiovascular, pulmonary, or neurological disease or disorder

Up to 15 people will be enrolled in the study.

What happens if I join this study?

If you join the study, you will: be asked to complete two experimental sessions at the VA ECHCS/University of Colorado Applied Biomechanics Lab; each session on a separate day at the

same time of day, and requiring approximately 2 hours of time. You will be asked to ride a stationary bicycle ergometer (Retül Müve, Specialized Bicycle Components Inc., Boulder, CO) at a fixed power output (1.5 W/kg) and complete a series of experimental trials over two days. On each day, we will measure your height, weight, and limb segment lengths. Then, we will place reflective markers on your legs and torso using double-sided tape. These markers will allow us to track your body position using our motion capture system. We will also record the forces you exert on each pedal using force-measuring pedals. Further, we will measure your leg muscle activity using wireless electrodes that will be placed over your muscles using double-sided tape. Finally, we will measure your metabolic rates from the air that you breathe out into a mouthpiece. Immediately after each trial, we will ask you to rate your satisfaction using a Visual Analog Scale and comfort, fit, effort, etc. with a questionnaire.

On Day 1, we will perform a custom bike fit for you according to a protocol developed by Retül for non-amputees (Specialized Bicycle Components Inc., Boulder, CO). Using this protocol, we will systematically vary saddle height and fore-aft position, handlebar vertical and fore-aft position, and alter cleat placement within the shoe for a prosthetic forefoot pedal attachment position, using a conventional crank arm length of 172 mm. Then, we will measure the biomechanics and metabolic rates while you ride using the initial fit and three taller pylon lengths for your affected leg in increments of 6.8 mm using a typical pedal attachment position beneath the forefoot. Then, using the optimal (most efficient) pylon length, we will measure the biomechanics and metabolic rates while you ride using three shorter crank arm lengths for your affected leg in decrements of 6.8 mm using a typical pedal attachment position beneath the prosthetic forefoot.

On Day 2, we will repeat the protocol of Day 1, but have you use a pedal attachment position beneath the pylon for your affected leg. We will randomize the order of days and trials within a day.

For each trial, we will ask you to ride at a set power output for 6 minutes while we measure your motion, forces, muscle activity, and metabolic demands. You will be given at least 6-minutes of rest between trials and will be asked to perform a maximum of seven trials per day. The total time commitment for this study is approximately 4 hours; 2 hours per day over 2 days.

All procedures are for research purposes only.

What are the possible discomforts or risks?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unexpected) risks also may occur.

Discomforts you may experience while in this study include:

Potential Risks.

1. There is a potential risk of physical discomfort from wearing any type of prosthesis.
2. The adhesive used for motion analysis markers and electrodes may produce slight discomfort.

3. The metabolic analysis mouthpiece and nose clip may produce slight discomfort.
4. Confidential information about participants will be collected as part of this study; therefore, there is a risk of disclosure.

Protections against Risks (corresponds directly to the Potential Risks listed above).

1. If you become fatigued, you may ask to rest or stop the study at any time.
2. Before participating in a study, you will be asked if you have any adhesive allergies and if you do, the reflective markers can be placed over tight-fitting clothing.
3. You may ask to remove the mouthpiece and nose clip, rest or stop at any time.
4. Significant efforts will be made to guard against the disclosure of confidential information. All data collected will be de-identified so that your identity is protected; however, the data collected poses no apparent risk to your privacy. We will implement a data and safety-monitoring plan to ensure your privacy. To de-identify your data, you will be given a unique code, and only the research team will have access to the key (linking the code to participant identifiers), which will be kept in a locked cabinet in a locked office. The key will be destroyed upon study completion.

Other possible risks include:

There is a risk that people outside of the research team will see your research information. We will do all we can to protect your information, but it cannot be guaranteed.

Risks of the usual care you receive are not risks of the research and are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about how different prosthetic and bicycle configurations affect the performance of people with a below the knee amputation. This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks. During each experimental session, you will get a modest amount of physical exercise and learn about how your musculoskeletal system functions. You will be able to use and test multiple prosthetic and bicycle configurations, and will get a recommendation for your optimal configuration at the end of the study. The testing of prosthetic and bicycle configurations will advance our understanding of how people with below the knee amputations bicycle, is intended to enable these people to bicycle with better symmetry and effort, improve their fitness and function, and have a choice to return to active duty.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

This research is being sponsored by the Department of Veterans Affairs.

Will I be paid for being in the study?

You will be paid $25.00 for each visit in this study.

It is important to know that payments for participation in a study is taxable income. Denver Research Institute will be disbursing payments.

Will I have to pay for anything?

There will be no cost to you for participation in this study. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged nor your insurance billed, for research-related interventions or procedures that are required by the protocol.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be withdrawn from the study?

The study doctor may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

Every reasonable safety measure will be used to protect your well-being. The Eastern Colorado Health Care System will provide necessary medical care and treatment for any injury that is a result of participation in this study for veterans. Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about an injury related to the research, call Dr. Alena Grabowski at 303-492-5208 or 720-435-4270.

Who do I call if I have questions?

The researcher carrying out this study at the VA is Dr. Alena Grabowski. You may ask any questions you have now. If you have any questions later you may call Dr. Alena Grabowski at 303-492-5208 or 720-435-4270. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, concerns or complaints about this research study, please call the Colorado Multiple Institutional Review Board (COMIRB) office at 303-724-1055. This is the Board that is responsible for overseeing the safety of human participants in this study. If you want to verify that this study is approved, please contact the VA Research Office at 720-857-5094.

Who will see my research information?

Taking part in this study will involve collecting private information about you. We will keep all research records that contain your identifiable health information, confidential to the extent allowed by law. Written information about you (e.g. this consent form) will be kept in a locked filing cabinet within the PI's locked office (Clare Small Building, room 103). Identifiable data will not be shared with anyone outside of the immediate research team. Data security for storage and transmission for electronic data stored on desktop computers will be managed via a secure network and password access. Power-on passwords will be established for all portable computing devices. Electronic data (non-identifiable health information) that is collected during experimental sessions will be stored on computers protected with passwords and only accessible to the research team. We will be collecting social security numbers. You can withhold your social security number and still participate.

We will try to keep your medical records confidential, but it cannot be guaranteed. Records that identify you (including your medical records and the consent form signed by you), may be looked at or portions of your records copied that identify you by others. These include:

- Federal agencies such as the Food and Drug Administration (FDA), the General Accountability Office (GAO), the Office of the Inspector General, Office for Human Research Protections (OHRP), and the Office of Research Oversight (ORO) that protect research subjects like you, may also copy portions of records about you.
- People at the Colorado Multiple Institution Review Board
- The investigator and research team for this study
- The sponsor (group paying for the study), study monitors or agents for the sponsor
- Officials at the institution where the research is being conducted, and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Our local VA Research and Development Committee
- University of Colorado Boulder Applied Biomechanics Lab

Information about you will be combined with information from other people taking part in the study. We might talk about this research study at meetings. We might also print the results of this

research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

We will ask you to sign a different form that talks about who can see your research records. That form is called a HIPAA Authorization form. It will mention companies and universities who will see your research records.

You have the right to request access to your personal health information from the Investigator.

The HIPAA Authorization form that you will also be asked to sign will state when or if it expires. However, you may withdraw this authorization for use and disclosure of your personal health information by providing written request to the Investigator. If you withdraw the HIPAA Authorization form, the Institution, the Investigator, the research staff, and the research Sponsor will no longer be able to use or disclose your personal health information from this study, except so far as that they have already relied on this information to conduct the study.

Photography and Video Recordings.

Pictures and/or video recordings may be taken of you during the study with your permission. Images and recordings of you could be used for scientific presentations. Any images or recordings that include identifiable information, such your face, will be masked to maintain confidentiality. All images and recordings will be kept on a password-protected computer that only the research team will have access to.

Is there other information I need to know

- **Disclosure of Results.** You will receive a report of your optimal orthotic or prosthetic configuration upon completion of the study.

- **Re-contact.** If you wish to be re-contacted for future research, we may contact you from within the VA **or** outside of the VA as you indicate below:

☐ Yes, I am interested in being contacted to participate in future studies. ____Initials

☐ No, I am not interested in being contacted to participate in future studies. ____Initials

Agreement to be in this study

I have read this form or it has been read to me. A member of the research team has explained the study to me and answered my questions. I have been told about the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told that I do not have to take part in this study. My refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Dr. Alena Grabowski at 303-492-5208 during the day and at 720-435-4270 after hours. If any medical problems occur in connection with this study, the VA will provide the necessary medical care.

I choose to participate in this study. A copy of this consent form will be placed in my medical record. If I am not a veteran, a health record will be created for me in the VA computerized patient record system (CPRS) to include my research records.

Subject's Signature: _____ Date:_____

Print name: _____

Consent form explained by: _____ Date: _____

Print name: _____

Investigator: _____ Date: _____

Print name: _____

----------Use the following only if applicable----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent, must sign the following statement, and check the appropriate box:

Witness Signature: _____ ***Date:*** _____

Print Name: _____

☐ ***Witness of Signature***
☐ **Witness of Consent Process**