

# **INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY**

## **Prosthetic Attention in Lower Limb Prosthesis Users**

### **What is this study about?**

The reason we are doing this study is to learn more about the attention or mental effort needed to use a prosthesis. Our goal is to develop a new questionnaire to measure prosthetic attention. We are looking for volunteers who use a lower limb prosthesis to help us identify the types of questions that tell us most about the attention needed to use a prosthesis. You can take part in this study if you regularly use a lower limb prosthesis to transfer or walk.

### **What will you be asked to do?**

If you agree to take part in this study, we will ask you to complete one survey. The survey includes questions about you, such as your age and education, as well as questions about your amputation, your prosthesis, your health, your physical abilities, and your experience with wearing a prosthesis. Examples of questions included in the survey are:

“How much attention do you have to pay to your prosthesis while...

stepping off a curb?”

walking through a busy parking lot?”

sitting down on a chair without armrests?”

You are free to not answer any question you choose. You may answer the questions on the computer or on paper. You decide which you would rather do. The entire survey will take about 30 minutes to complete. You do not have to answer any question for any reason. If you have not completed the questions within one week, a research staff member will contact you to see if you still want to be in the study.

Before starting the survey, you will be asked to provide your name and contact information. You must provide this information in order to participate. We will only use this information to check for duplicate surveys, contact you if we need to clarify any of your responses, and to send your payment for participating in this study. For quality assurance purposes, we will also collect your Internet Protocol (IP) address if you complete the survey on the computer.

### **Why might you want, or not want, to participate?**

Some of the survey questions in the survey may be upsetting to you. You are free to ask any questions or share your concerns with the research staff while completing the survey. The survey may feel long, and you may become tired. You may take a break anytime you need to. Because this study involves collecting identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. To minimize this risk, we will assign you a study number. All of the information we collect will be stored in a secure manner.

The alternative to taking part in this study is to not take part in this study.

You will not directly benefit from participating in this study. The study results may help us improve questionnaires used by health care providers and make them more relevant to your experiences. Your participation in the study will assist researchers nationwide in making questionnaires used in health care settings shorter, more meaningful, and easier to answer.

You will be offered payment for your participation in this study. If you have a U.S. or Canadian address, we will mail you a \$40 check for completing the survey.

### **How will we protect the information you provide?**

All the information you provide will be confidential. We will protect the information we collect about you by assigning a unique study code to your responses. The link between your name and this code will be kept in a safe place.

The study team will use REDCap, an online database, to collect and store your information. The information in REDCap will include information that will identify you, such as your name and contact information. REDCap is a secure system for data storage used in many research studies. REDCap requires a username and password to log-on and is encrypted. REDCap is stored on a secure server. The study team is able to choose who has access to log-on to REDCap and see your information. Access will only be given to study team members.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be

examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The information that we obtain from you for this study might also be used for future studies. We will remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. You can choose to withdraw your information from future use or sharing. However, once the de-identified information has been shared, you may not be able to withdraw the information.

### **Other information about this study.**

There are no costs for you to be in this study. Taking part in this study is voluntary. You can stop at any time. You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

We will keep your name and contact information in order to contact you about possible future research.

The study team and the University of Washington are receiving financial support from the United States Department of Defense (DOD) under a subcontract from Virginia Commonwealth University.

### **What can you do if you want more information?**

We are asking you to be in a research study. The purpose of this information sheet is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called “informed consent.”

**Talk to the study team.** We are here to help you understand the study. Please ask us any questions you may have, even about things that are not in this document. It is our

responsibility to give you the information you need to make a decision and to give you time to think about whether or not you want to sign up. If you feel you have been harmed by participating, you can contact us about that too.

**Talk to someone else.** If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research subject, or to report problems or complaints about the study, contact the UW Human Subjects Division.

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