

**UNIVERSITY OF WASHINGTON**  
**INFORMATION STATEMENT – Survey Study**

**Fall-related health outcomes in lower limb prosthesis users**

**Researchers:**

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**RESEARCHER'S STATEMENT**

We are asking you to be in a research study. The purpose of this form is to explain the study and help you decide if you want to be in the study or not. Please read the form carefully. If you have any questions, you may contact us at uwcorr@uw.edu or 800-504-0564 (toll free). You might want to ask for more information about why we are doing this study and what you will be asked to do if you decide to be a part of it. You may ask questions about the possible risks and benefits and what your rights are as a volunteer. You may ask any question about the research and ask for help understanding any part of it that is not clear to you. When all your questions are answered, you can decide if you want to be in the study or not. If we get any new information about the study or there are changes to the study in any way, we will let you know right away. This process is called 'informed consent.' You may keep this form for your records.

**PURPOSE OF THE STUDY**

The reason we are doing this study is to develop better fall-related health surveys for people who use lower limb prostheses. We want to find the best way to ask prosthesis users about confidence they have in performing activities without falling (fall-related self-efficacy), feelings they have about falling (fall-related anxiety), actions they take to avoid falling (fall-related avoidance behaviors), and restrictions in life they may experience due to thoughts of falling (fall-related interference). You can take part in this study if you use a lower limb prosthesis regularly to transfer or walk.

**STUDY PROCEDURES**

If you agree to take part in this study, we will ask you to complete one survey. You will be asked some questions about you, such as your age and education, and questions about your amputation, prosthesis, health, physical activities, and your experience with falls and fall-related health outcomes. Examples of the questions are, "How often does the thought of falling cause you to feel afraid?" and "To avoid falling, how often do you hold onto something?" and "How much does the thought of falling keep you from living the life you want?" 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 survey will take about 45-60 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.

Participants may also be invited to complete a second survey with additional questions about fall-related experiences. The second survey will take about 45-60 minutes to complete and is optional.

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.

### **RISKS, STRESS, OR DISCOMFORT**

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.

### **ALTERNATIVES TO TAKING PART IN THIS STUDY**

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

### **BENEFITS OF THE STUDY**

There are no direct benefits to you for being part of 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.

### **SOURCE OF FUNDING**

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

### **CONFIDENTIALITY OF RESEARCH INFORMATION**

The researchers will keep your responses 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.

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**

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. If you want to withdraw from this study or think you have

been harmed by participating in this study, please contact Dana Wilkie or Alexandra Hinson at uwcorr@uw.edu or 206-221-2414.

There are no costs for you to be in this study. If you have a U.S. or Canadian address, we will mail you a \$25 check for completing the survey. We will pay participants an additional \$25 for completing the second survey.

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

If you have questions later on about the study, you can ask one of the investigators listed above. If you have questions about your rights as a research subject, you can call the University of Washington Human Subjects Division at 206-543-0098.