UNIVERSITY OF WASHINGTON
CONSENT FORM

Development of a Mobility Performance Measure for Prosthesis Users

Researchers:
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Researchers' statement
We are asking you to be in a research study. The purpose of this consent form 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." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY
The purpose of the study is to develop a better test for measuring mobility in lower limb prosthesis users. In this study, we will collect information about how you perform different types of activities that may be conducted in a clinic.

STUDY PROCEDURES
If you choose to take part in this study, we will ask you to attend a single session at a local clinic or meeting space. You will first be asked to complete a survey. The survey will ask your age, ethnicity, income, military status, education, and height and weight. We will also ask questions about your amputation, health and the things you do with your prosthesis. Next, you will be asked to perform several mobility activities. These activities require that you do things you might normally do like sitting still, rising from a chair, walking short distances, or stepping over objects. You may be asked questions about the tasks that you perform (for example, "Were any part of the instructions difficult to understand?", "Is this an activity that you would do in your home?"). You will be asked to rest between each activity, and you may rest at any other time you wish. The entire session will last between 60 and 90 minutes. You may choose not to answer any of the questions you are asked or not complete any of the activities you are asked to perform.

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. We ask you to perform mobility activities tests for between 30 and 60 minutes during the study session. Some people may become tired or unsteady. You will be asked to rest between each test. You can also take a break or sit down whenever you like. A researcher trained in spotting participants will be near you, and will

be available to support you if you require assistance. If the researcher notices you appear tired or unsteady, he or she may ask you to rest or end the study visit.

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

You will not directly benefit from participating in this study. However, the activities included in this study may help clinicians and researchers to better assess prosthesis users' mobility.

SOURCE OF FUNDING

The study team is receiving financial support for this research from the National Institutes of Health (NIH).

CONFIDENTIALITY OF RESEARCH INFORMATION

The information you provide to us during the study is confidential. We will protect the information we collect about you using a unique code. The link between your name and this code will be kept in a safe place apart from the information we collect about you.

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.

Study data that do not identify you may be shared with other researchers at the University of Washington or from other institutions.

We have a Certificate of Confidentiality from the federal the National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We cannot use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- State or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

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.

You are responsible for your transportation to and from the study session. We will pay any parking costs while you are attending study session. You will be offered payment for your participation in this study. You will receive $50 for completing the session. All payments will be made by a check mailed to you.

We would like your permission to take photographs and videos of you during this study so that we have an accurate record. You do not have to give this permission to participate in this study. Please indicate below whether or not you give your permission. If you give your permission we will ask you to complete a separate form that details under what conditions we can use your photograph and video. For example, we may ask for your additional permission to use the photographs and recordings outside this research study. We may want to use them publicly and keep them indefinitely. We will give you opportunity to review the photographs and recordings before giving your permission. You may request that we destroy any videos or pictures we collect at any point during or after the study. If we publish the results of this study, we will not use your name or any other health information that identifies you.

RESEARCH-RELATED INJURY

If you think you have been harmed by participating in this study, contact Andre Kajlich at 1-800-504-0564 or uwcorr@uw.edu right away.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

☐ I give my permission for the researchers to photograph the study procedures as described above in this consent form.

☐ I give my permission for the researchers to videotape the study procedures as described above in this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher; Subject