

## Prosthetic Needs and Outcomes in Veterans

We are inviting you to take part in a research study. We are doing this study to learn about:

- Your quality of life since your amputation.
- Your experience with your prosthesis.
- Your experience with the prosthesis fitting process.

Our goal is to understand how Veterans are using their prostheses and what factors are associated with better and worse outcomes. Ultimately, we hope this information will help improve clinical care and identify services that can improve the quality of life for Veterans with amputations.

The purpose of this Information Statement is to provide you information you will need to help you decide whether to take part in the study. Your participation in this research study is voluntary. Please read this form carefully. You may ask questions about the purpose of the research, what we are asking 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 take part in the study or not. You may choose not to participate or may leave the study at any time without penalty or loss of benefits to which you are entitled.

This study may be a good fit for you if:

- You have an amputation, even if you got the amputation after you served in the military
- You have ever used a prosthesis

Even if you don't receive care at a VA, you may still be eligible.

### 1. WHY IS THIS STUDY BEING DONE?

The VA provides care to over 45,000 Veterans with amputations. With your help, we want to understand:

- Your experience in doing activities you want to do since your amputation;
- Your experience and satisfaction with your prosthesis;
- Your experience with care you've received after your amputation; and
- How VA could better care for Veterans with an amputation.

The information you give will help guide the VA to identify areas of need and help to improve services for Veterans with amputations. We are hoping that 650 Veterans nationwide who have had an amputation will complete the survey.

### 2. WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

#### Principal Investigator:

Alyson Littman, PhD

#### Co-Investigator:

Keren Lehavot, PhD

#### Study Coordinators:

Rachel Thomas, MPH

Krista Dashtestani, BA

#### Study Telephone Number:

206-277-5020

or toll-free at 1-800-329-8387  
extension 65020

If you agree to participate, we will ask you to complete a 45- to 60-minute survey. You can access the survey online by going to the website link included in your invitation letter and entering the unique username and password combination that has been assigned to you. Please make sure to do it when you know you will have enough uninterrupted time. You can also call our study office if you prefer to complete a hardcopy, mailed version of the survey.

You can opt-out of participating in the study by mailing back the enclosed opt-out card. If we do not hear from you (i.e., you do not return the opt-out card and do not complete the online survey), we may send you another letter and/or give you a call.

Some of the survey questions will be directly about your prosthesis; others will be about your health more generally, including your mental health and trauma history. For example, some questions we will ask about include:

- *When did you get your first prosthesis?*
- *How many hours per day do you currently wear your prosthesis?*
- *Over the last 2 weeks, how often have you felt down, depressed, or hopeless?*
- *When you were in the military, did someone ever use force or threat of force to have sexual contact with you against your will?*

### **3. ARE THERE ANY RISKS OR DISCOMFORTS?**

None of the information we collect about you will be shared with anyone outside of the study team; however, there is a risk of loss of confidentiality if the information shared were linked to your identifiers (e.g., your name). The online survey will only be linked to a unique username and password combination that have been assigned to you and will not include any of your identifying information.

Any activity on the internet involves risk and, in using your own computer, you should take the normal precautions of ensuring that your system is running the most current version of your browsing software, that you have up-to-date virus protection, and that you implement a software or hardware firewall to protect your computer and yourself. By ensuring your computer has up-to-date security measures, you can reduce the risk to yourself, but risk cannot be totally eliminated.

There are also potential psychological risks, including discomfort or distress associated with sharing information about your experiences. Some of the questions are of a personal nature, including questions about your thoughts, feelings, and personal difficulties. You are free to not answer any questions you wish.

Please visit our “Resources” page for a variety of resources for Veterans and Veteran amputees, should they be helpful: <https://ampvetresources.questionpro.com/>

### **4. ARE THERE ANY BENEFITS?**

You will not benefit directly from being in this study. Your participation may assist others in the future by helping us to better understand how best to care for Veterans with amputations.

### **5. WHO WILL SEE MY INFORMATION?**

You will complete the online survey on the QuestionPro website. QuestionPro is not a VA system and is not managed by the VA. It is a commercial site that includes a level of data security and privacy that meets VA standards. When going to the site for the first time, we recommend that you take the time to review the site (<https://www.questionpro.com>) and read the privacy policy of the site (<https://www.questionpro.com/security/>). Be sure you feel comfortable answering questions on the site.

The information collected for this study will be kept confidential and will not be disclosed outside of the VA unless required by law or regulation. Any manuscripts or presentations of the data will include only de-identified data. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Puget Sound Institutional Review Board (IRB), our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. This oversight is needed to make sure the quality and integrity of the study are preserved.

The document connecting your name and username/password combination will be kept in a protected file that is physically separated from any information we collect from you. Your responses will be reported only in de-identified format. Once this study is completed, we will not use your data, or the study code linking it to you for any additional research. We will keep your data and code in a secure database in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed). We will take every precaution to secure the information you provide.

#### **6. WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THE STUDY?**

We will mail you a \$25 check 8-12 weeks after we receive your completed survey. In order for us to process your check, we will use your social security number that is in your medical chart.

#### **7. WHO CAN I TALK TO ABOUT THE STUDY?**

In the event of a research-related injury, or if you have questions, comments, or concerns about the study, please contact us at **206-277-5020 or toll-free at 1-800-329-8387, extension 65020.**

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Institutional Review Board (IRB) Office at 206-277-1715.

If you are experiencing thoughts of harming yourself or others, call the national **Veterans Crisis Hotline** at 1-800-273-8255 (press 1) or go to their website at <http://www.veteranscrisisline.net>

*Thank you for reading this letter and thinking about participating in this study.*