INFORMATION SHEET FOR: Needs, Preferences and Functional Abilities of Veterans and Service Members with Upper Limb Amputation

You are being asked to participate in a survey funded by the Department of Veterans Affairs (VA). The Principal Investigator for this project is Linda Resnik, PT, PhD, an employee of the Providence Veterans Administration (VA) Medical Center. Your involvement in this study will include one or more survey. With this research we hope to learn more about how to assess your satisfaction with your prostheses, your ability to perform certain activities, the usefulness of your prosthesis and your residual limb health. Your participation in this research study is voluntary. Please read the information below and decide if you wish to participate in our survey. If there is anything that is not clear, or you would like more details, call our study staff at 401-273-7100 X6535.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to develop questions that best address different aspects of quality of life and function for persons with upper limb loss or difference. This study will provide evidence to help consumers and clinicians make informed choices about upper limb prosthetic devices. You are being asked to participate in this survey because you are a person with major upper limb (arm) loss or difference.

WHAT WILL HAPPEN NEXT?

You will receive a call from the study team at the Providence VA Medical Center or the Office of Survey Research at the University of Massachusetts Medical School to participate in a phone survey. You may be asked questions about difficulty you experience when using your prosthetic device, residual limb health and overall satisfaction with your device. You may skip any questions that you do not want to answer. We expect the phone survey to last about 45 minutes to 1 hour, and it may be monitored for quality assurance purposes. After you have completed the survey, we will mail you a $20 gift card as a token of our appreciation.

You have the right to withdraw from the study at any time by notifying Dr. Resnik over the phone or in writing.

You may also be asked to participate in another part of our study if you qualify. You do not have to take part in other study activities if you do not want to.

ARE THERE ANY RISKS OR DISCOMFORTS?

The questions in the interview or survey are not expected to result in any discomfort. If you are uncomfortable answering any question, you have the option of skipping that question. The only known risk from this study is an accidental disclosure of your responses. We will make every effort possible to protect the confidentiality of the information you provide to us by keeping your responses separate.
from your name or other personally identifiable information. Information will be stored in a restricted folder, and the only people who will have access to these data will be approved study staff.

ARE THERE ANY BENEFITS?

While there are no direct benefits to you from your taking part in this research study, the information we collect might help change prosthesis reimbursement policies and available technology.

WHO WILL SEE MY INFORMATION?

The information you provide during the survey will be protected in the following ways:

- Survey responses will not be linked to your name or any other identifying information.
- All electronic records for this project will be kept on the Providence VAMC (PVAMC) research server in a restricted folder. The telephone survey data will be filed securely at the University of Massachusetts until it can be securely transferred to the PVAMC. All computers used for this study are password protected, and only approved study staff will have access to the data.
- Your answers will be combined with information from other people taking part in this study. We will write about the combined data we have gathered. You will not be identified in any talks or papers about this study. Some deidentified data will be shared with our research partners at Boston University who are assisting us with analyses.

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 Central Institutional Review Board, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

You will receive a $20 gift card in the mail for each survey you complete.

WHO CAN I TALK TO ABOUT THE STUDY?

If you have any questions, complaints, and/or concerns about the survey, please contact the study Principal Investigator, Dr. Linda Resnik, at 401-273-7100 x2368. If you have questions about your rights as a study participant, or you want to make sure this is a valid study, you may contact the VA Central Institutional Review Board at 877-254-3130. This is the board that is responsible for overseeing the safety of human participants in this study.

HOW CAN I OPT OUT OF THE STUDY?

If do not wish to participate in the survey, you can call our study staff, Josie Airoldi, at 401-273-7100 x6535 or you can let an interviewer know once they call you to ask for your participation. We will take your name off the study list if you do not wish to participate.