

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

Study Title: Patient Preferences for Attributes of Risk and Benefit of Prosthetic Devices
for Limb Loss

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This is a survey research study about limb prosthetic devices. The study researchers, Leslie Wilson, Ph.D. from the UCSF Departments of Medicine and Pharmacy, Yelena Ionova, Pharm.D. or a graduate researcher from the UCSF Department of Pharmacy, will explain this study to you.

Research studies include only people who chose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have an existing limb loss.

Why is this study being done?

The purpose of this study is to learn more about how limb loss patients may choose limb prosthetic devices.

This study is being supported with funding from the Burroughs Wellcome Fund.

How many people will take part in this study?

Approximately 200 patients will be taking part in this study.

What will happen if I take part in this research study?

If you agree, the following activities will occur:

- You will be guided to take a three-component survey administered on a computer by Leslie Wilson or a graduate researcher.
- The first component will ask you basic questions about you and your limb loss background, the level of activities you are able to do, and symptoms you might have experienced. This component will take you about 10-15 minutes.
- The second component will ask you to think about two different lists of prosthetic factors and choose a list that you like best. A handout with a description of these factors will be emailed to you to read. This component will take you about 10-15 minutes.
- Leslie Wilson or the graduate researcher will contact you by phone, email, or mail at a later point in time if they have any questions about your answers or participation.
- We will contact you to retake the same survey in 4-6 weeks, and again at 3 months post last survey in order to see how your preferences change over time.
- **Study location:** These survey components will be completely administered online at your computer at home.

How long will I be in the study?

Participation in the survey study will take a total of about 25-30 minutes at one point in time. You will be contacted to retake the same survey 4-6 weeks later, and again at 3 months post last survey.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell any of the study researchers right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- We do not expect any side effects or risks, but you might be tired from taking the 30-minute survey. You can stop at any time.
- For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals and other people with limb loss learn more about patient's preferences for prosthetic devices.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. A unique identifier will be used when you take all three components of the survey. This unique identifier is linked to your name and contact information in a separate database, and will only be used if the researchers need to contact you after the study. Only the researcher conducting the follow-up will access your name and contact information. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

Will I be paid for taking part in this study?

You will receive a small compensation (\$10) for completion of the survey at each time point.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care the way you usually do.

Who can answer my questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact the researchers Leslie Wilson, PhD at Leslie.Wilson@ucsf.edu (415) 990-1012 and Yelena Ionova, PharmD at Yelena.Ionova@ucsf.edu.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at (415) 476-1814.

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date

Participant's Signature for Consent

Please PRINT participant's name _____

Please include participant's preferred CONTACT information _____

Please provide your printed name and address for mailing thank you:
