INFORMED CONSENT FORM

Upper Limb Prosthetic User Needs and Preferences Study: Focus Groups

We are asking you to participate in a research study titled "Upper Limb Prosthetic User Needs and Preferences." This study is being led by Eugene Civillico, Ph.D. and Heather Benz, Ph.D., FDA Center for Devices and Radiological Health. Melissa Clark, Ph.D. is conducting the focus groups. Please ask the research staff if you have any questions or would like any part of this form explained.

Taking part is voluntary

Your participation in this research is voluntary. You may refuse to participate before the study begins, discontinue at any time, and/or skip any questions or procedures that make you feel uncomfortable. There will be no penalty and no effect on compensation earned before withdrawing. Your participation in this study may be stopped if you fail to follow the study procedures or if the investigators feel that it is in your best interest to stop participation.

What the study is about

The purpose of this research is to learn about the needs and preferences of people with amputation. This study will help guide the development of new prosthesis technologies and regulatory decision-making.

What we will ask you to do

We will ask you to answer questions about your experiences with amputation and prostheses and ask your opinions on several new prosthesis technologies. Some of these questions will be asked in a homework assignment, which you may complete on paper or online. Other questions will be asked in a focus group. You will participate in one focus group session, which will take about two hours.

Risks and discomforts

We do not anticipate that participating in these research activities will put you at risk or cause you discomfort. Information you provide may be shared with Food and Drug Administration or governmental authorities if you or someone else is in danger, or if we are required to do so by law.

Benefits
Information from this study may help to develop new devices that increase quality of life and functionality for upper limb amputees. The results will not directly benefit the participants. There is no obligation to participate.

Compensation for participation
You will receive compensation worth $10 for completing the homework and $30 per hour spent in the focus group session (anticipated compensation value $70).

Audio Recording
We will be recording audio of your verbal responses for the duration of the focus group session in order to refer to your responses as needed. Your audio recordings will be destroyed after they have been transcribed for analysis.

Privacy, Confidentiality, and Data Security
All records obtained from this study are confidential, to the extent permitted by law. The FDA's Institutional Review Board may have access to the study records. Your participation in this study will remain confidential, and your identifying information will not be stored with your data or audio recordings. Servers and computers where the data and audio recordings are stored are encrypted and password protected. Only people authorized by the Principal Investigator will be granted access to the data.

The data will be used for research and educational purposes, such as teaching, publications, and/or presentations and may be viewed by students, other trainees, and professional colleagues. In any sort of report we make public, we will not include any information that will make it reasonably possible to identify you.

If you have questions
The principal investigator conducting this study is Eugene Civillico, a Health Physicist at the Center for Devices and Radiological Health in the US Food and Drug Administration.

If you will be participating using the WebEx telepresence software, you may contact Heather Benz (contact information below) with any questions, or you may ask questions during your WebEx training session. WebEx participants will submit their statement of consent using a digital signature when completing online homework to prepare for the focus group.

If you are participating in an in-person focus groups, please ask any questions you have now. If you have questions before or after your session, you may contact:

Heather Benz
heather.benz@fda.hhs.gov
301-796-8884

If you have any questions or concerns regarding your rights as a subject in this study, or wish to file complaints or report possible coercion to participate in this study, you may contact:

Research Involving Human Subjects Committee (RIHSC)
FDA/OC/OCS/OSI
10903 New Hampshire Avenue
Building 1 Room 4213
Silver Spring, MD 20993-0002
RIHSC@fda.hhs.gov and 301-796-9605

You may request a copy of this form to keep for your records.

You have not waived any legal right to which you are legally entitled by signing this form.

Statement of Consent

I have read the above information and have been allowed to ask questions and express concerns that have been satisfactorily answered and addressed by the research staff. I understand the purpose of this study as well as the potential benefits and risks involved. I certify that I am at least 18 years old, and I hereby give my informed and free consent to take part in this study.

Your Signature_____ Date_____

Your Name (printed)_____

Signature of person obtaining consent_____ Date_____

Printed name of person obtaining consent_____