# Informed Consent to Take Part in a Research Study

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| Study Title | **Functional Outcomes of Voice Recognition Prosthesis** |
| Investigators | Todd Farrell, PhD<br>**Liberating Technologies, Inc.**<br>325 Hopping Brook Road, Suite A<br>Holliston, MA 01746<br>(508) 893-6363 |
| Sponsor | National Institutes of Health |
| NEIRB # | 120180305 |

### What is the purpose of this form?

You are being asked to participate in a research study conducted at Liberating Technologies, Inc. (LTI). It is important that you read the following explanation of the proposed procedures. This form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes your right to withdraw from the study at any time. A member of the study staff will read through the consent with you and discuss all the information. When you think you understand the study, you will then be asked if you agree to take part. If you agree, you will be asked to sign this consent form. Once you sign it, we will give you a signed and dated copy to keep.

You may show this consent form to family and friends before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study.

### Why is this study being done and what is being studied?

Prosthetic terminal devices include split-hooks, task-specific devices, and multi-articulating hands. With conventional two-site myoelectric control there are limits to the number of operating modes that can be accessed by a given user and control of multiple devices requires more effort. LTI is designing a voice recognition prosthetic control module that combines and extends control of these technologies. The voice recognition module has not been approved by the FDA and its use in this study is experimental. The voice recognition control module will be retrofit onto subjects' existing prosthesis socket.

This study is focused on testing the functionality of the voice recognition prosthesis in comparison to existing control methods. If successful, the new technologies may become clinical products for prosthesis users.

### What do I need to know about this study?

A total of up to twenty (20) volunteers will be subjects in this experiment. Participants will manipulate everyday objects with prosthetic terminal devices through functional outcome tests.



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## What will happen during this study?

This study will consist of two visits for an anticipated time of 4 hours each. These visits will take place at LTI in Holliston, MA. During the first visit, you will perform the tests with your usual prosthetic control, while during the second visit you will test with voice control. During the study you will doff your personal terminal device and utilize the devices being tested. If you do not use a prosthesis, you will wear a prosthesis simulator brace. You will test two configurations including:

a. Multi-articulating hand with voice recognition control module disabled (Visit 1)
b. Multi-articulating hand with voice recognition control module enabled (Visit 2)

You will be instructed on completing activities of daily living (ADLs) and functional outcome tasks that involve manipulating common objects (beans, coins, pegs, spoon, cloth, clothespins, etc.), as defined in upper limb functional tests (such as UNB Test of Prosthetics Function, Jebsen-Taylor, SHAP and Peg Board). Each sub-task in the functional test will be timed and scored.

You will be allowed time to become familiar with the multi-articulating hand and voice recognition control module. Once you are comfortable with both the control of the prosthesis and the performance of the functional outcome measures, testing will begin, and data will be recorded.

You will repeat the tasks with each of the configurations. The devices will be controlled with the same signals used in your personal prosthesis in addition to your voice. You will be given a break between each condition and are able to stop at any time during the testing.

If it is difficult for you to come to LTI for the test visits, we may perform testing at your home or location of your choosing, if the site has the space and other requirements necessary for testing to be performed safely and effectively.

We may request you return for a follow up visit(s) if testing could not be completed or to determine how consistent your performance is.

## What are the potential risks of being in the study?

You may experience muscle fatigue or a tired voice from the controlling the devices. Should you feel any discomfort or fatigue from the training, you should stop and take a break. The risks to pregnant people and fetuses are unknown and therefore pregnant people should not participate in the study.

## Does being in this study provide any benefit?

There is no direct benefit to you for participating in this study.
The data collected will guide the development of a voice recognition prosthetic control module.

## What happens if I have a research related injury?

Liberating Technologies, Inc. assume no responsibility to pay for any injuries that you might receive as a result of participating in this research study. No funds have been set aside for payments or other forms of compensation (such as for lost wages, lost time, or discomfort). If you suffer a physical injury as a result of your participation in this study, you may choose to seek medical care in the same way as you would normally. If your insurance does not cover the cost, then you may be responsible for this cost. However, you do not give up any of your legal rights by signing this consent form.


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### Will I be paid for being in this study?

You will receive $40/hour and reimbursement for study travel by mileage at the IRS rate per mile driven.

### Do I have to be in this study?

Your participation in this study is voluntary. You are free to withdraw consent and discontinue participation at any time. Your refusal to participate or your withdrawal from the study will involve no penalty or loss of benefits to which you are entitled.

### Can I be removed from the study without my permission?

The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit. Data obtained in this experiment will become the property of the investigators and Liberating Technologies, Inc. If you withdraw from the study, data already collected from you will remain in the study.

### Who will have access to my study and/or medical information?

Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or its designee and, under certain circumstances, the Food and Drug Administration (FDA) and New England Independent Review Board (NEIRB) will be able to inspect and have access to confidential data that identifies you by name. Any publication or presentation of the data will not identify you. By signing this consent form, you authorize the study investigators to release your study records to the sponsor, the FDA, and the IRB.

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

### Consent to Photograph and/or Videotape

By consenting to this study, you give your permission for the investigators to take photographs and/or videotape recordings of you during the experiments. Footage will consist of filming the experiments as you perform each of the tasks and will focus on recording your arm. These images may be used in medical or scientific publications and presentations. With your consent to the study you give permission to the investigators to publish and present photographs and videos of you with the condition that they conceal your face and other identifying marks, such as birth marks or tattoos. The investigators will not reveal your name or any other personal information about you. Photos and video will be stored indefinitely in password-protected computers and locked cabinets accessible only to the investigators. If you do not consent to photographs and/or videotaping as stated above, you may not participate in the study. If you don't agree to be photographed or videotaped, you cannot be in the study.

### Data Reuse and Contribution of Your Data to a Public Data Archive

The data from this experiment will also be contributed to publicly available databases and/or reused by the study investigators in future research. The purpose of this data reuse is to share your data with other researchers (or reuse the data ourselves) to make further advances in medicine, science and teaching. Your data could be used for many different purposes. Most researchers will gain access to your data over the Internet. Before contributing your data, all information that identifies you as a subject in this experiment (including your name) will be coded using a random code. The only way to relate the code to your identifying



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information is by a “key” that the study investigators will maintain private. We will never reveal your identity, unless required to do so by law. The public database will not provide any direct access to your identity.

### Who do I contact if I have questions about the study?

If you have questions, complaints or concerns about the study, you can contact:

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| **Todd Farrell,** Ph.D. |
| (774) 233-0873 |

If you have questions about your rights as a research subject, or other questions, concerns or complaints about the research, you can contact NEIRB at 1-800-232-9570.

## VOLUNTEER'S STATEMENT

You agree that you have been given a chance to ask questions about this research study. These questions have been answered to your satisfaction. If I have any more questions about taking part in this study, you may contact:

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| **Todd Farrell,** Ph.D. |
| (774) 233-0873 |

Liberating Technologies, Inc. are being paid by the sponsor for your participation in this study.

Your participation in this research project is voluntary. You may quit the study at any time without harming your future medical care or losing any benefits to which you might be entitled. The investigator in charge of this study may decide at any time that you should no longer participate in this study.

By signing this form, you have not waived any of your legal rights.

You agree to participate in this study. You will be given a copy of this signed and dated form for your own records.

_____ _____
Study Participant (signature) Date

_____
Print Participant's Name

_____ _____
Person who explained this study (signature) Date



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