NC STATE UNIVERSITY

Informed Consent for Participation in Research

Adult Consent Form for Amputee Participant

Title of Study: R21: An Easy-to-use, iNtelligent, Affordable LinEr (ENABLE) System for Socket Fit Assessment **(eIRB # 23949)**

Principal Investigator(s): Ming Liu (mliu10@ncsu.edu and 919-515-8541

Funding Source: National Institute of Health

What are some general things you should know about research studies?

You are invited to take part in a research study. Your participation in this study is voluntary. You have the right to be a part of this study, to choose not to participate, and to stop participating at any time without penalty. The purpose of this research study is to validate the performance of the Easy-to-use, iNtelligent, Affordable LinEr (ENABLE) System, which is designed to permit prosthetists to estimate the pressure distribution on your residual limb by observing the color of the ENABLE pad after walking on the ground.

You are not guaranteed any personal benefits from being in this study. Research studies also may pose risks to those who participate. You may want to participate in this research because the ENABLE system has the potential to help prosthetists improve their capability to control pressure distribution on the residual limb and improve the comfort of the prosthetic sockets. You may not want to participate in this research because the related tasks may lead to fatigue (likely) or fall (very unlikely) and we will expose your residual limb to a thermal environment that is higher than what you usually experience and may lead to skin damage.

Specific details about the research in which you are invited to participate are contained below. If you do not understand something in this form, please ask the researcher for clarification or more information. A copy of this consent form will be provided to you. If, at any time, you have questions about your participation in this research, do not hesitate to contact the researcher named above or the NC State IRB office. The IRB office's contact information is listed in the *What if you have questions about your rights as a research participant?* section of this form.

What is the purpose of this study?

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Am I eligible to be a participant in this study?

There will be approximately 10 participants in this study.

In order to be a participant in this study, you must agree to be in the study and meet the following inclusion conditions:

- Be 18 years or older
- Unilateral transtibial amputee
- At least 1 year of experience using your prosthetic leg
- Have used the current socket for at least 6 months without a significant skin issue or multiple modifications by your prosthetists.
- Can comfortably walk 3 mins without pausing to rest
- The fibula length on the residual limb must be greater than half of the length of the fibula on the unaffected side

You cannot participate in this study if you do not want to be in the study or meet the following exclusion criteria:

- Cognitive or visual impairment that affects your ability to provide informed consent or to follow simple instructions during the experiments
- Neuropathy observed on the residual limb
- Currently pregnant

What will happen if you take part in the study?

If you agree to participate in this study, you will be asked to do all of the following:

1. Fill out a survey verbally, which details your age, height, gender, time of, and reason for amputation. This will happen in your first visit to our lab.
2. Participate a touch sensitivity test on your residual limb to ensure that you can self-monitor the condition of your residual limb. During this test, a researcher will use a monofilament to touch your residual limb and you will need to answer whether you can feel the touch of the monofilament without looking at it. This will happen in your first visit to our lab.
3. Work with a certified prosthetist to make a testing socket for this study. The prosthetist will duplicate your current socket and ask you wear it with your own prosthetic leg. The prosthetist will also conduct modifications if you do not like the socket. It will take 2-5 visit to the office of the prosthetist to finish this part.
4. Walk with the developed ENABLE system, a standard sensing pad, and the testing socket. The reading of the sensing pad and pictures of the ENABLE system before and after walking will be recorded. The ENABLE system is an experimental device, which has not been approved by the FDA. This stage will include two to three in-person visits to the lab.

5. Answer survey questions verbally to evaluate the comfort of the ENABLE system.

The total amount of time that you will be participating in this study is about 10 hours, including standard socket manufacture, fitting, and walking trials.

The first visit to the lab is to obtain consent and conduct touch sensitivity tests on the residual limb to ensure that you are able to self-monitor during the experimental procedure. Then the whole experimental procedure will be conducted through three sets:

Set I procedure includes a standard socket construction, which requires 2-3 visits to the office of a local prosthetic company. A certified prosthetist will build a test socket and a customized liner to maximize the socket fit and comfort and conduct needed alignment of the prosthetic leg. Unless it is necessary, all testing sockets will be a duplication of your everyday socket.

Set II will test the accuracy of the constructed ENABLE system compared to pliance® (Novel, Germany), a commercially available sensor pad. First, we will mount both sensing systems on you. The pliance® sensor grid will be mounted on your residual limb directly using medical tape. After you don the ENABLE sensing pad, we will register two sensing systems. In the end, you are required to don the testing socket and walk continuously, so the measurement of the developed prototype could be stabilized. Pictures of the ENABLE will be taken and compared with the recorded pressure signals from the pliance® grid.

Set III will test whether information from the ENABLE leads to appropriate socket-fit-assessments based on the response of experienced prosthetists when shown the pressure distribution measured by the ENABLE under different fit conditions. You will be exposed to five socket fit conditions: good and additional foam pads at four different areas shown in a random sequence. The size of the pad at each location is selected by the prosthetists based on the shape and size of your residual limbs.

Under each fitting condition, you will go through three trials. In each trial, you will walk continuously until the color of the sensing pad has stabilized. After taking high-resolution digital pictures, which cover most of the sensing area of the ENABLE, we will let you rest until the optical pattern of the ENABLE fades completely before starting a new trial.

Recording and images

If you want to participate in this research, you must agree to be photographed. Most of the photo will cover your residual limb and some of them may cover your upper limb. Your head will not be included in the photos to protect your identity. If you do not agree to be photographed you cannot participate in this research.

Risks and benefits

There are minimal risks associated with participation in this research. The risks to you as a result of this research include:

1. The risk of falling during the task performance in the experiments. There is no challenging task in the experimental procedure and only level-ground walking at your comfortable walking speed will be conducted using your own prosthetic leg. If you worry about the risk of falling, we can protect you using overhead tracks and fall-arrest harnesses, which cover the whole area of the walking course in our laboratory. Handrails and additional protection will be provided if requested. During the socket manufacture procedure, you will be supervised by certified prosthetists.

2. The repeated task performance could result in fatigue. We will provide mandatory breaks during the experimental procedure and you can ask for a break whenever you need one.

3. Unexpected pressure on residual limb. Unexpected pressure may be seen on your residual limb, but usually lasts less than 5 minutes and is generated by soft materials instead of hard objects. You can stop anytime if you feel that the pressure is beyond a small discomfort.

To make sure that you are able to conduct self-monitoring of your residual limb, we will conduct touch sensitivity measurement on the surface of the residual limb in your first visit to our lab. 10g monofilaments will be pushed towards your skin and you will be required to identify touch location without seeing the monofilament. Passing this test will ensure that your capability to detect abnormal load on your skin is good.

4. Unexpected thermal damage on the residual limb. The ENABLE system relates the pressure with local temperature change, which may raise temperature to maximum 45°C (113°F). Exposure to this temperature for a long time may increase the risk of skin damage on your residual limb. Although the experimental procedure will be much shorter than the exposure time, which can cause thermal damage. It is necessary to conduct self-monitoring continuously during the experimental procedure.

5. to prevent and minimize impact of a lea of any personal identifiable informationAll collected data will be coded. A coded ID number will be assigned to link the collected data and each recruited subject's identity. The subject ID number will be stored in a linkage file to link ID with subject identity information. The linkage file will be password protected and stored in a locked cabinet in the PI's office. Any identifiable info (your name and contact information) will be stored in a locked cabinet and made accessible only to the PI. As soon as records with identifiers are no longer needed they will be disposed of by shredding. To ensure sensitive data is protected, team members will be trained and be responsible for ensuring data protection.

Right to withdraw your participation

You can stop participating in this study at any time for any reason. If you want to stop your participation when you are not in an experimental procedure, please contact Dr. Ming Liu at 919-515-8541, at mliu10@ncsu.edu, or to 1412 Engineering Building III, Raleigh, NC, 27695. If you want to stop during the experimental procedure, you can tell the experimenters directly about your decision. If you choose to withdraw your consent and to stop participating in this research, you can expect that the researcher(s) will redact your information from their data set, securely destroy your data, and prevent future uses of your information for research purposes.

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Confidentiality, personal privacy, and data management

Trust is the foundation of the participant/researcher relationship. Much of that principle of trust is tied to keeping your information private and in the manner described to you in this form. The information that you share with us will be held in confidence to the fullest extent allowed by law.

Protecting your privacy as related to this research is of utmost importance to us There are very rare circumstances related to confidentiality where we may have to share information about you. Your information collected in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety. In other cases, we must report instances in which imminent harm could come to you or others.

How we manage, protect, and share your data are the principal ways that we protect your personal privacy. Data that will be shared with others about you will be de-identified

> **De-identified**. De-identified data is information that at one time could directly identify you, but that we have recorded this data so that your identity is separated from the data. We will have a master list with your code and real name that we can use to link to your data. When the research concludes, there will be no way your real identity will be linked to the data we publish.

Future use of your research data

To help maximize the benefits of your participation in this project, by further contributing to science and our community, your de-identified information will be stored for future research and may be shared with other people without additional consent from you. The funding agent, National Institute of Health, also requests that the de-identified data are made accessible to the public on the https://www.clinicaltrials.gov.

Compensation

For your participation in this study, you will receive $25/hour with $50 minimum per visit. The payment will be made in direct deposit. If you do not have a bank account, we will arrange gift card payment. The maximum payment you could get from participating in the project is $500.00.

If you withdraw from the study prior to its completion, you will be paid for the current visit with $50 minimum.

Emergency medical treatment

If you are hurt or injured during the study session(s), the researcher will call 911 for necessary care. There is no provision for compensation or free medical care for you if you are injured as a result of this study.

What if you are an NCSU student?

Your participation in this study is not a course requirement and your participation, or lack thereof, will not affect your class standing or grades at NC State.

What if you are an NCSU employee?

Your participation in this study is not a requirement of your employment at NCSU, and your participation or lack thereof, will not affect your job.

Sponsorship and Funding

This research is funded by the National Institute of Health. This means that the sponsor is paying the research team for completing the research. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study. Dr. Ming Liu is an inventor from NC State University. If this approach is successful at some point in the future, NC State University may receive financial benefits. If you would like more information, please ask the researcher listed in the first page of this form about the funding and sponsorship.

What if you have questions about this study?

If you have questions at any time about the study itself or the procedures implemented in this study, you may contact the researcher, Dr. Ming Liu at 919-515-8541, at mliu10@ncsu.edu, or to 1412 Engineering Building III, Raleigh, NC, 27695.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. This website will not include any information that can directly identify you but it will include a summary of this study's results within a year after the study has completed. You can search the clinical trials website at any time to review this study's results once they are posted.

What if you have questions about your rights as a research participant?

If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact the NC State IRB (Institutional Review Board) office. An IRB office helps participants if they have any issues regarding research activities. You can contact the NC State IRB office via email at irb-director@ncsu.edu or via phone at (919) 515-8754.

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Consent To Participate

By signing this consent form, I am affirming that I have read and understand the above information. All of the questions that I had about this research have been answered. I have chosen to participate in this study with the understanding that I may stop participating at any time without penalty or loss of benefits to which I am otherwise entitled. I am aware that I may revoke my consent at any time.

Participant's printed name _____

Participant's signature _____ Date _____

Investigator's signature _____ Date _____