**UNIVERSITY OF MICHIGAN**

**CONSENT TO BE PART OF A RESEARCH STUDY**

**Date Approved: 3/24/2026**

**NCT Number: NCT07254247**

**Brief Title:**

# A Unique Body-Powered Terminal Device With Enhanced Grasping Capabilities for Individuals With Upper Limb Loss

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## 1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

**Study title:** A Unique Body-Powered Terminal Device with Enhanced Grasping Capabilities

**Principal Investigator:** Deanna Gates, Ph.D., School of Kinesiology, University of Michigan

You are invited to take part in a research study that aims to develop and test a novel body-powered prosthetic terminal device. This form contains information that will help you decide whether to join the study.

### 1.1 Key Information

Things you should know:

- The purpose of the study is to evaluate and assess the performance of a novel body-powered prosthetic device with able bodied users using a prosthetic emulator to complete functional assessments.
- The study will consist of 2 visits that may last up to 3 hours.
- Testing will take place at the Rehabilitation Biomechanics Laboratory, located in the School of Kinesiology Building on central campus at the University of Michigan.
- Risks or discomforts from this research include possible fatigue and skin irritation.
- There are no direct benefits to you from your participation.
- You will be compensated $20/hour for your time.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

## 2. PURPOSE OF THIS STUDY

The purpose of this study is to assess performance of a novel body-powered prosthetic hand compared to an existing device with able-bodied individuals. We will obtain outcomes such as completion time and task performance. We will ask you to interact with a device that simulates using an upper limb prosthesis. After practicing, we will ask you to complete the function assessments.

## 3. WHO CAN PARTICIPATE IN THE STUDY

### 3.1 Who can take part in this study?

You may take part in this study if you:

- Are between the ages of 18-80
- Are proficient in English

- Able to demonstrate proper functioning and safety of the terminal device
- Have no visual or mental impairments
- Have no history of neurological or musculoskeletal disorders

**3.2 How many people are expected to take part in this study?**
We will enroll 8 healthy adults in this study.

## 4. INFORMATION ABOUT STUDY PARTICIPATION

**4.1 What will happen to me in this study?**

You will visit the Rehabilitation Biomechanics Laboratory located on the University of Michigan campus in Ann Arbor for two testing sessions lasting up to 3 hours. After you have signed this consent form, we will record your height and weight along with other basic demographic information.

A researcher will fit you with a body-powered prosthetic emulator. This is a system that will enable you to control a prosthetic end-effector, which is like a hand, but different in appearance. You will complete testing with two different end-effectors in random order. You will be able to acclimate to each end effector for about 10-minutes. During this time, you will be coached on techniques to properly open and close the device. Then, you will be asked to complete functional assessments where you reach and grasp and manipulate different objects. Throughout this process, you will be given rest periods as needed, and you will be reminded that continued participation in the study is voluntary.

Throughout the visits, researchers will take notes related to your behavior and outcomes
related to the different upper limb tasks. To validate these notes and obtain more accurate results, we will take video-recordings of you completing different tasks. These videos can be viewed only by study team members and will not be shared outside of that without your permission. Please note that video recordings are required for participation in this research study. This ensures accuracy in capturing data and quantifying performance during the tasks and verify this measure between the study team members. Videos may be used for reporting purposes, however, your face and any identifiable marks will be blurred to protect your privacy. Additionally, some deidentified videos may be used for presentations.

**4.2 How much of my time will be needed to take part in this study?**

You will be required to take part in two testing session, lasting up to 3 hours. The session will be conducted at the Rehabilitation Biomechanics Laboratory within the School of Kinesiology Building at the University of Michigan

## 5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

**5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?**

*The known or expected risks are:* The physical risks to you are no different than risks you experience every day. There is always a small risk that you could experience muscle fatigue or exhaustion. There is a risk of skin irritation while wearing the prosthetic simulator.

The researchers will try to minimize these risks by:

- To minimize the potential risk of fatigue, you will be allowed to take frequent breaks.
- To reduce the risk of skin irritation, the researchers will adjust the prosthetic simulator to your best fit.

There is also the potential risk of loss of confidentiality through participation in this study. Every effort will be made to keep your information confidential. However, this cannot be guaranteed. The information we collect that has your name on it will be kept in a locked room in a locked cabinet. The video of you will not be shown to anyone outside the study team without your permission. If we do choose to use your video, and we receive your permission; we will distort the video so that your face is not recognizable.

As with any research study, there may be additional risks that are unknown or unexpected.

**5.2 How could I benefit if I take part in this study? How could others benefit?**
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

**5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?**
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study; it is possible that you may be asked to sign a new consent form that includes the new information

## 6. ENDING THE STUDY

**6.1 If I want to stop participating in the study, what should I do?**
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

## 7. FINANCIAL INFORMATION

**7.1 Will I be paid or given anything for taking part in this study?** You will receive $20/hour for your participation in the study. Your compensation will be disbursed using a UM Human Subject Incentives Program (HSIP) gift card, which will be sent to your home address.

If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

**7.2 Who could profit or financially benefit from the study results?**

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

Little Room Innovations, LLC. is developing the device used in this study. If successful, the device may be marketed and sold in the future.

## 8. PROTECTING AND SHARING RESEARCH INFORMATION

**8.1 How will the researchers protect my information?**
You will not be identified in any reports on this study. Your research information will be stored in a locked cabinet. Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likey to allow someone other than the researchers to link the information to you. Records will be confidential to the extent provided by federal, state, and local law.

Your research information will be stored electronically on the cloud; the term “cloud” refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards.

**8.2 Who will have access to my research records?**

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
  Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly
  - Learn more about adverse effects
  - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about the results.

The results of this study could be published in an article or presented at a scientific meeting, but would not include any information that would let others know who you are.

### 8.3 What will happen to the information collected in this study?

We will keep the information we collect about you during the research for future research projects. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. Data collected will be kept secure until it is destroyed and will be de-identified before sharing with others. Once the study is complete, all identifiable data will be destroyed.

The results of this study could be published in an article or presentation but will not include any information that would let others know who you are.

### 8.4 Will my information be used for future research or shared with others?

We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

## 9. CONTACT INFORMATION

**Who can I contact about this study?**

Please contact the researchers listed below to:

- Obtain more information about the study.
- Ask a question about the study procedures.
- Report an illness, injury, or other problem (you may also need to tell your regular doctors).
- Leave the study before it is finished.
- Express a concern about the study.

Research Study Coordinator: Kayla Russell-Bertucci
Mailing Address: School of Kinesiology Suite 1200, University of Michigan, 830 N University Ave, Ann Arbor, MI 48109-1048
Telephone: 734-764-3832
Email: kaylarb@umich.edu

Principal Investigator: Deanna Gates, Ph.D.
Mailing Address: School of Kinesiology 1205, University of Michigan, 830 N University
Ave, Ann Arbor, MI 48109-1048
Telephone: 734-647-2698
Email: gatesd@umich.edu

**If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:**

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 2144
Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

## 10. YOUR CONSENT

**Consent/Assent to Participate in the Research Study**

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study.*

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____