NC STATE UNIVERSITY

Amputee Participant Consent Form

Title of Study: Comparing Intact and Residual Amputated Neuromuscular Physiology
(eIRB # 24436)
Principal Investigator: He Huang (hhuang11@ncsu.edu and 919-515-8541)
Funding Source: Jackson Family Distinguished Fellow Fund
NC State Faculty Point of Contact: He Huang (hhuang11@ncsu.edu and 919-515-8541)
Collaborating Researchers: Robert Hinson (rmhinson@ncsu.edu), Brendan Driscoll (bhdrisco@ncsu.edu), Noah Rubin (nrubin@ncsu.edu), Wentao Liu (wliu29@ncsu.edu), Joseph Berman (jmberman@ncsu.edu), Ming Liu (mliu10@ncsu.edu)

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 investigate differences in neuromuscular physiology in residual amputated muscle following amputation compared to non-amputated muscle. We will do this by measuring muscle activation and shape, along with joint kinematics and torque during different tasks, like activation of your ankle muscles, standing, swaying, sitting down and standing up, squats, heel-raises, and walking on a treadmill. These tasks will be completed while sitting without a prosthesis, or when needed, with both a passive prosthesis and a powered prosthesis with a socket appropriately fitted.

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 investigation has the potential to help inform design of powered prosthesis controllers to improve their reliability and functionality. You may not want to participate in this research because the related tasks may lead to fatigue (somewhat likely) or fall (very unlikely).

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 principal 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?
The purpose of the study is to evaluate differences in neuromuscular physiology in residual muscle following amputation compared to intact muscle in both non-functional and functional tasks involving muscle activation and motor control.

How many people will be in the study?
There will be approximately 80 participants in this study: 40 who have lower-limb amputations and 40 who do not.

Am I eligible to be a participant in this study?
To be a participant in this study, you must agree to be in the study and you:

- Are 18 years of age or older

- Live in the United States
- Are a unilateral lower-limb amputee
- Have lower limb length from the knee to where the amputation occurred at least 10cm long
- Can walk across low-level environmental barriers such as curbs, stairs, or uneven surfaces unassisted and without much difficulty

You cannot participate in this study if you do not meet the inclusion criteria listed above OR:

- You have any cognitive, visual, or balance impairments that affects your ability to provide consent or to follow instructions during the experiments
- You have had a stroke
- You have heart disease
- You had skin lesions/incomplete healing following amputation
- You have ulcers
- Have lower limb length from the knee to where the amputation occurred less than 10cm long
- Weigh 450 pounds or more (for harness safety)
- Have a girth/waist circumference more than 49 inches (124.4 cm) (for harness safety)
- Have allergies to adhesives

What will happen if you take part in the study?

If you agree to participate in this study, you will be asked to come to the PI's laboratory and BME gait lab (1404 Engineering Building III) on the NC State University campus in Raleigh, NC for up to 16 visits. Each visit will be up to a maximum of 4 hours. You will provide us some demographic information before your first visit and pass the initial screening. Before every visit, you will need to pass an online COVID-19 screening that is taken before you arrive.

A minimum of 48 hours will separate each testing session. More detail on these sessions is described below.

Note that during the sessions you will repeat tasks multiple times. A warm-up is incorporated into every session, and we will make you take breaks between trials. We will check in with you regularly, and you are welcome to tell us when you want a break or stop at any time for any reason.

The following sensors/devices will be attached for the study. The sensors will be fixed via a double-sided adhesive, self-adhesive wraps, or straps. All are easily removable and adjustable for your comfort. Wearing shorts is recommended to simplify the process of adding sensors.

1. **Muscle Activation While Sitting** (Session 1):
    a. Muscle Activity Sensors:
        i. **Number**: 4
        ii. **Placement**: 1 on the front and back of the leg below your knee.
2. **Muscle Activation While Sitting** (Sessions 2-3):
    a. Muscle Activity Sensors:
        i. Same as Session 1
    b. Joint Dynamics Device:

   i. Your non-amputated foot will be strapped into a platform that measures how much you are pulling/pushing or moving your ankle. On tasks thinking about activating your phantom limb, we will ask you to the match activities with both limbs so that we can record what you are thinking about with your phantom limb via your non-amputated foot.
c. Muscle shape sensors:
   i. **Number:** 2 ultrasound probes
   ii. **Placement:** On the front and back of your leg, switching legs between sessions.

3. **Prosthesis Fitting** (Sessions 4-6):
   a. Muscle Activity Sensors:
      i. Same as Session 1
   b. Socket:
      i. A trained prosthetist will cast and fit a socket to you designed to safely fit the muscle activity sensors.
   c. Powered Prosthesis Device
      i. A trained prosthetist will assist aligning the casted socket with a powered prosthesis we have in the lab.
4. **Functional Tasks** (Sessions 7-16):
   a. Muscle Activity Sensors:
      i. Number: 18
      ii. Placement: 1 on the front and back of the leg below your knee, 2 on the front of your leg above your knee, 1 on the back of the leg below your knee (5 per leg), 2 on your arm above and below your elbow (4 per arm)
   b. Socket:
      i. Fitted in earlier sessions
   c. Powered Prosthesis Device
      i. Fitted and aligned in earlier sessions
   d. Movement measurement markers:
      i. **Number:** 40 in total.
      ii. **Placement:** 4 on your head, 5 on your torso, 7 on each arm, 5 on your hips, 3 on each leg, 1 on each of your ankles, toes and heels (on your shoe).
   e. Harness:
      i. A harness attached to the ceiling will be used to catch you case of any fall during the experiment.

During each visit you will be asked to do all the following:

1. **Muscle Activation While Sitting (Sessions 1-3):** Come to the lab for 3 initial sessions, where you will:
   a. Practice muscle activation of your ankle muscles while wearing sensors measuring your muscle activity and shape. There will be a brief calibration to your maximum effort to ensure muscle activation will be less than maximum effort throughout the rest of the study.
   b. We will provide you with visual biosignal feedback to guide you how to control your muscles.

2. **Prosthesis Fitting (Sessions 4-6):** Attend a session where a trained prosthetist will cast your residual limb for a socket, followed by 1, 2, or 3 fitting (up to 3 total) sessions with your socket and a powered prosthesis with a certified prosthetist. Each visit will last up to two hours. The prosthetist will duplicate your current socket and ask you to wear it with a powered prosthesis. The prosthetist will also conduct modifications if you do not like the socket to ensure fit and your comfort while wearing the socket.

3. **Functional Tasks (Sessions 7-16):** Once the fit has been finalized, you will come to the lab for up to 10 additional sessions for functional tasks. During each visit, you will be asked to practice modulating and controlling the activation of your amputated and non-amputated muscles. After training and practicing activating and controlling your muscles, we will then ask you to conduct the following tasks:
    a. Quiet standing (not moving)
    b. Postural sway (leaning forward and backward)
    c. Sitting down and standing up repeatedly
    d. Squatting
    e. Standing up on your toes (heel-raises)
    f. Walking on a treadmill at your preferred walking speed

    Handrails (both left and right) will be always available to allow balance support if needed, and additional harness protection is available.

    We will ask you to do all tasks with your passive prosthesis and a powered prosthesis to determine if the powered device improves functional performance. At times, we will give you auditory feedback to help you time your motion, and visual biosignal feedback to guide you on how you place your weight between your legs.

    We expect you to come in for up to additional 10 sessions for these activities to account for adaptations in performance when using a powered prosthesis, and post-training evaluations of your amputated and non-amputated muscles. This estimate also accommodates necessary setup and take-down time that subjects must be present for, while maintaining reasonable individual session periods.

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.

The total amount of time that you will be participating in this study is up to 58 hours.

Recording and images

If you want to participate in this research, you must agree to be photographed and video recorded. Your head will not be included in the photos or videos to protect your identity. If you do not agree to be photographed, you cannot participate in this research. Any identifiers, such as tattoos and birth

marks, will be removed or blacked out from video and photo if they are captured before they are used for publication, presentation, and future research purposes.

Additional recordings include:

- Muscle activity (electrical signals from your muscles)
- Ultrasound images (your muscle shape)
- Joint torque output (how much torque you are outputting on our dynamometer)
- Joint motion (positions of markers or inertial sensors that we place on your joints to capture dynamics). The motion recording cameras can only see reflective markers and cannot be used to identify you.
- Force plate ground reaction force (how hard your pressing/stepping on the treadmill).

If you do not agree to the above recordings, you cannot participate in this research.

Risks and benefits

There is no direct benefit to you as a participant. However, there may be a benefit to the general community of lower limb amputees in time.

The risks to you because of this research include:

1. A breach of your confidentiality will rarely occur. All data with identifiers will be stored in a locked cabinet or, if digital, with password protection, encryption, and only accessed with VPN. As soon as records with identifiers are no longer needed, they will be disposed of by shredding. All collected data will be coded. A coded ID number will be assigned to link the collected data and each recruited subject. 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 PI's office. To ensure sensitive data is protected, team members will be trained and be responsible for ensuring data protection.

2. The risk of falling during the socket fitting and experimental sessions. During the socket manufacture procedure, you will be supervised by certified prosthetists acting as contractors who have experience being able to fit prostheses safely. In our laboratory, 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.

3. The repeated task performance could result in muscle fatigue, delayed onset muscle soreness, and in rare cases muscle injury. We will provide mandatory breaks during the experimental procedure, and you can ask for a break whenever you need one.

4. Minor skin irritation or discomfort due to the sensors and equipment you will wear during the experimental sessions. The adhesive tape for electrode and sensor fixation may produce minor irritation of the skin, which may cause discomfort. There is also the possibility of an allergic reaction to the adhesive tape. The possibility of irritation will be minimized by wiping

the skin with alcohol before and after application of the electrodes. We will ask you after each trial about your level of comfort, and you are encouraged to stop at any time. There is no consequence for ending testing at any point.

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, tell the faculty point of contact, Dr. He Huang (hhuang11@ncsu.edu or 919-515-8541). 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. This is possible in most, but not all, cases.

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 and NIH) 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 re-identifiable and, in some cases, identifiable.

Re-identifiable. Re-identifiable data is information that we can use to identify you indirectly because of our access to information, role, skills, combination of information, and/or use of technology. This may also mean that in published reports others could identify you from what is reported, for example, if a story you tell us is very specific. If your data is re-identifiable, we will report it in such a way that you are not directly identified in reports. Based on how we need to share the data, we cannot remove details from the report that would protect your identity from ever being figured out. This means that others may be able to re-identify from the information reported from this research.

Identifiable. Identifiable data is name and email information that directly links you to the data. This includes, but is not limited to, your name, e-mail, phone number, or other details that makes you easily recognizable to us and others. Identifiable data has your real identity directly on the compensation forms that are shared with us and other people.

Future use of your research data

Your information, even with identifiers removed, will not be stored or distributed for future research studies.

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Informed Consent for Participation in Research

Compensation

For your participation in this study, you will receive $25/hour with $50 minimum per visit, including visits with prosthesis fittings. The payment will be made in the form of a gift card payment. The maximum payment you could get from participating in the project is $1,450.00. 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 because of this study.

Sponsorship and funding

This research is funded by the Jackson Family Distinguished Fellow Fund. 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 results of the study. 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 faculty point of contact, Dr. He Huang (hhuang11@ncsu.edu or 919-515-8541).

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 University IRB office at IRB-Director@ncsu.edu, 919-515-8754, or fill out a confidential form online at https://research.ncsu.edu/administration/participant-concern-and-complaint-form/

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.

☐ **Yes, I want to be in this research study.**

Name_____

Phone Number: _____, Email: _____

Today's Date _____

☐

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No, I do not want to be in this research study.

Thank you for your consideration.

[Insert IRB approved COVID-19 addendum from the COVID-19 additional procedures packet]

BROAD CONSENT ADDENDUM

Title of Study where Broad Consent is Initially Sought: Comparing Intact and Residual Amputated Neuromuscular Physiology **(eIRB # 24436)**
Principal Investigator(s): He Huang (hhuang11@ncsu.edu and 919-515-8541)
Funding Source: Jackson Family Distinguished Fellow Fund
NC State Faculty Point of Contact: He Huang (hhuang11@ncsu.edu and 919-515-8541)
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This form asks you to make an important choice about the use of your re-identifiable information. It asks you to decide if you are willing to give your consent to the use of your re-identifiable information for future research.

If you agree, researchers in the future may use your re-identifiable information in many different research studies over an indefinite period of time without asking your permission again for any specific research study. This could possibly help other people or contribute to science. If you do not agree to allow your re-identifiable information to be used for future research, your re-identifiable information will not be kept for future use by anyone.

This form explains in more detail what saying “yes” or “no” to this use of your information will mean to you.

If you say “Yes” on this form

The researcher(s) will store, use and share your re-identifiable information, and may do so for the purpose of medical, scientific, and other research, now and into the future, for as long as they are needed. This may include sharing your re-identifiable information with other research, academic, and medical institutions, as well as other researchers, drug and device companies, biotechnology companies, and others.

If you say “yes,” there are no plans to tell you about any of the specific research that will be done with your re-identifiable information.

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By saying "yes," your re-identifiable information may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, pay you, or give any compensation to you or your family.

The main risk in saying "yes" is that your confidentiality could be breached. Through managing who has access to your re-identifiable information and through regularly updated data security plans, we will do our best to protect your re-identifiable information from going to people who should not have it.

Another risk is that if you say "yes," your re-identifiable information could be used in a research project to which you might not agree to if you were asked specifically about it.

You will not personally benefit from saying "yes" in this form. Saying "yes" in this form is not a condition of participating in the Comparing Intact and Residual Amputated Neuromuscular Physiology study, nor of your enrollment or employment at any institution.

If you say "no" or do not complete this form

The researcher(s) and institution(s) identified above will not store, use, or share your re-identifiable information beyond the purposes stated in the previous consent form that you agreed to and signed for the Comparing Intact and Residual Amputated Neuromuscular Physiology study.

If you want to withdraw your consent

You can stop participating at any time for any reason by stopping any research activity that you are doing or by contacting the faculty advisor for this research, Dr. He Huang, at hhuang11@ncsu.edu and 919-515-8541. You can expect that the researcher(s) will redact your re-identifiable information from their data set, securely destroy your data, and prevent future uses of your re-identifiable information for research purposes wherever possible. This is possible in some, but not all, cases.

If you have questions

Please ask the research team to explain anything in this form that you do not clearly understand. Please think about this broad consent and/or discuss it with family or friends before making the decision to say "Yes" or "No."

If you have any questions about this broad consent, please contact faculty advisor for this research, Dr. He Huang, at hhuang11@ncsu.edu and 919-515-8541.

If you want to discuss your rights as a person who has agreed to, refused, or declined to respond to an offer of broad consent or believe that your rights were violated as a result of your agreeing to this broad consent, please contact the NC State IRB Director at IRB-Director@ncsu.edu, 919-515-8754, or fill out a confidential form online at https://research.ncsu.edu/administration/participant-concern-and-complaint-form/.

Please select one option and provide your name and today's date

☐ **Statement of agreement**

I say yes. The future use of my data and this broad consent addendum is clear to me. I agree that my re-identifiable information can be used for other research studies. My participation is voluntary. I can withdraw my consent at any time without any penalty or loss of benefits to which I am otherwise entitled.

_____

Statement of agreement: Name

_____

Statement of agreement: Today's Date

☐ **Statement of refusal**

I say no. The broad consent addendum is clear to me. I do not give permission for my re-identifiable information to be kept or used for other research studies. **You can still participate in this research if you say no on this form.**

_____

Statement of refusal: Name

_____

Statement of refusal: Today's Date

[Consent addendum that copies the relevant sections of the IRB approved protocol details document and the images/videos for the amputee participants to review]