NC STATE UNIVERSITY

Informed Consent for Participation in Research

Consent Form for participants without any neurological disorders

Title of Study: Improving Balance and Energetics of Walking Using a Hip Exoskeleton **(eIRB # 24671)**

Principal Investigator(s): Varun Nalam (vnalam@ncsu.edu) and He Huang **(**919-515- 5218 and hhuang11@ncsu.edu)
Funding Source: None
NC State Faculty Point of Contact: He Huang **(**919-515- 5218 and hhuang11@ncsu.edu)
Collaborating Researchers: Qiang Zhang (qzhang25@ncsu.edu); Wentao Liu (wliu29@ncsu.edu) Ming Liu (mliu10@ncsu.edu); Abbas Alili (aalili@ncsu.edu); Michael Lewek (michael_lewek@med.unc.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 demonstrate the effectiveness of a hip exoskeleton device to improve stability and reduce exertion in participants. We will do this by attaching a robotic hip exoskeleton on the pelvis of the participants and using it to provide assistance during different tasks, like sit-to-stand, walking on a treadmill, level-ground walking, walking on a ramp, stairs climbing and descending, and so on. We will collect data on how your muscles move and react to the exercises that you will do as part of the research. In addition, a mask will be used for measuring metabolic cost. This mask will be attached on top of the surgical or N95 mask that you wear to comply with Covid protocols. The mask is disinfected and sanitized after every use. Apart from the robotic device, no other electrical simulation would be applied during the experiment.

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 research may lead to better balance and walking assistance in the paretic stroke community. You may not want to participate in this research because the related tasks may lead to fatigue and discomfort due to walking for a longer time. Further, you may experience tripping while walking even though falling over is prevented using a regulatory safety harness. Finally, wearing a mask on the face might cause some discomfort along with additional discomfort and possible irritation when sensors are stuck to your skin.

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(s) 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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The purpose of the study is to evaluate and validate different control approaches of a powered hip exoskeleton for improving balance and reducing exertion during walking for both people without any neurological disorders and people affected by paretic stroke.

How many people will be in the study?
There will be approximately 100 total participants in this study, but only 80 in your participant group.

Am I eligible to be a participant 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:

- Between 18 and 64 years old
- Live in the United States
- Able to understand study requirements and sign an informed consent
- Have full range of motion in your hip joint
- Able to walk normally without any assistance

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

- You cannot follow instructions or provide feedback due to cognitive or language limitations
- You had a stroke that affected your balance or walking
- You use an electronically controlled medical device, such as a pacemaker, implanted defibrillator, or drug pump
- You are pregnant
- You have numbness, tingling, muscle weakness, pain, or paralysis in any part of your body
- You can't walk or balance without help from a person or a tool, such as a walker or cane
- You have limited movement in your hip or ankle
- You have any skin related allergies or irritation to adhesives
- You have blood circulation, heart, metabolic, or cognitive disorders, including but not limited to:
    - Peripheral vascular disease
    - Pitting edema
    - Heart disease
    - Diabetes (uncontrolled)
    - Seizures
    - Cognitive diagnoses which affect your ability to process information

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 5 visits. Each visit will be up to 4 hours long, with 3 hours of that time engaged in physical movement. You will provide us with some demographic information before your first visit and before the initial screening. Before every visit, you will need to pass an online COVID-19 screening that is taken before you arrive.

During each visit, you will:

1. Be asked to walk normally without wearing any devices and equipment.

2. Place and wear sensors, tape, and reflective markers on your lower legs and/or torso. The sensors will measure your muscle activity, the tape will make sure the sensors stay in place, and the reflective markers will help us record how your body moves during the lab visit.
3. The following sensors will be attached for the study. Wearing shorts is recommended to simplify the process of adding sensors.
    a. Muscle activity sensors: **Number:** 7 per limb. **Placement**: One on the lower hip, two in the back of the lower thigh, two in the front of the lower thigh, one on the shank and one on the calf. The area will be cleaned by an alcohol prep pad before attaching the sensor.
    b. Movement measurement sensors: **Number:** 7 in total. **Placement:** One on the lower back, one on each thigh, shank and foot.
    c. Movement measurement markers: **Number:** 22 in total. **Placement:** Two on the lower abdomen, two on the lower back, three on each thigh, calf and foot.
    d. Oxygen usage sensor: The sensor is worn like a mask which has a 2-inch tube. It measures the oxygen being breathed in and out to estimate how much oxygen is used. It does not obstruct any air flow.
4. You will also be asked to wear a robotic hip exoskeleton. The hip exoskeleton is a robotic device that you wear like a backpack and strap to your waist and thighs. The device has motors in parallel with your hips and applies a force on your thighs to help you perform tasks.
5. While wearing the exoskeleton, sensors, tape, and reflective markers, you will:
    a. Learn how to walk wearing all of the devices and equipment.
    b. While wearing the devices and equipment, you will perform activities of daily life, including:
        i. Walking on level ground
        ii. Walking on a treadmill
        iii. Walking on a ramp
        iv. Move from sitting to standing
        v. Move from standing to sitting
        vi. Climbing stairs
        vii. Descending stairs
6. The exoskeleton will provide additional force during each task to help you do them with more ease and will learn the right amount of force to apply to help you perform the task.
7. You will perform the tasks for no more than 3-5 minutes each trial for a total of 10 trials with sufficient rest between trials.

The following procedures are experimental: We will be using a novel robotic hip exoskeleton device to develop optimal assistance control to help you perform various daily activities. The device is attached to your upper body like a backpack and is also strapped across each of your thighs independently. The device is developed at the lab as a prototype and is being evaluated for efficacy. To apply the assistance, the robotic hip exoskeleton device is connected to a DC power supply of 24 volts. The supply is provided with shutoff and fuses to prevent excess voltage or current. So any possibility of electric shock is minimal. Further, the force applied by the motors is also limited by the power supply, so the risk of injury is minimized.

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 about 20 hours, which includes 5 visits to our lab (4 hours for each visit) over an 8-week period.

Recording and images

If you want to participate in this research, you must agree to be photographed and video recorded. If you do not agree to be photographed and video recorded, you cannot participate in this research. Additionally, we record your motion using reflective markers. The motion recording cameras can only see reflective markers and cannot be used to identify you. If you do not agree to be motion recorded, you cannot participate in this research. Video will be taken of your torso and lower limbs and will not include your face. 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 (with your consent) future research purposes.

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. A breach of your confidentiality is unlikely to occur, but possible. 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. There is likely to be skin irritation due to the use of self-adhesive surface electrodes and/or small motor vibrators on the skin. However, this will be minimized by cleaning the skin before and after the experimental procedure. If the skin is irritated, the electrodes will be immediately removed, and the study will be terminated.
3. Although electrical motors are used for the powered hip exoskeleton, we do not anticipate any safety-related issues with this protocol. The two main risks are that the motor applies a force to the hip causing discomfort and injury, and the possibility of electric shock. The permitted current and voltage is limited by the power supply, which prevents any unreasonable application of force and an emergency shut off is implemented to minimize both risks.
4. You may fall during the experimental procedure. Although the consequence of fall is very high, we minimize the risk by providing additional protections. All the experimental procedure will be conducted under the coverage of a railing system designed to protect you from fall. During the task, in which the railing system could not provide full protection, such as stairs and sit-to-stand, additional rails or walkers will be provided.
5. You may experience fatigue during the experimental procedure. Although the chance is low, you may experience minor fatigue and muscle pain. To prevent related risks, rest time is provided between trials and you can stop anytime when you feel discomfort or for any other reason.

There are no direct benefits to your participation in the research. The indirect benefit is to help members of the stroke survivor community to improve their balance and reduce exertion during multiple locomotion tasks.

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. He (Helen) Huang at 919-515- 5218, at hhuang11@ncsu.edu, or to 4402D 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 data from their data set, securely destroy your data, and prevent future uses of your data for research purposes wherever possible. This is possible in some, 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 that we have 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, NSF) 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, re-identifiable, and identifiable.

> **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. This will be most of the data we publish, as we plan to aggregate the findings into groups of 3 or more people, so it would be hard to know who an individual participant is.
>
> **Re-identifiable.** Re-identifiable data is information we can 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. In this research, the re-identifiable data is the images and videos made during the lab visits. While we will crop out your face and blur identifying details such as tattoos and jewelry, we cannot promise that your identity won't ever be figured out. This means that others may be able to re-identify from the information reported from this research.

Identifiable. Identifiable data is 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 information that is shared with us and other people. For the purposes of this research, the identifiable data that will be shared about you is your name, email, phone number with researchers for the purposes of compensation and communication to set up the study.

Future use of your 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. Your re-identifiable and identifiable information will not be kept or shared for future research by anyone.

Compensation

For your participation in this study, you will receive $15/hour per visit. The payment will be made through a bank debit card. If you do not have a bank account, we will arrange gift card payment. Less than half hour will be counted as half hour; more than half hour, but less than one hour, will be counted as an hour.

If you withdraw from the study prior to its completion, you will be paid for the study duration in which you participated.

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.

What if you are an NCSU student?

As a part of the general population, you may participate in the research while under no obligation to. 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?

As a part of the general population, you may participate in the research while under no obligation to. 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.

Research collaborations

This research project is a cooperative effort between the following entities: North Carolina State University and University of North Carolina, Chapel Hill.

Inventions and patents

He Huang is an inventor of the hip exoskeleton that is part of this research in which it is being used to assists locomotion. He Huang, Ming Liu, and Varun Nalam are also a part owners of Avex Motion to whom the patent for hip exoskeleton has been licensed. If the technology is licensed at NC State University, a ICF disclosure in Sophia (the Office of Research Commercialization database at the

University) must state that the University and the inventor may benefit from the invention. If this patent or approach is successful at some point in the future, NC State University and He Huang may receive financial benefits. If you would like more information, please ask the researcher(s) listed at the top of this form.

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. He (Helen) Huang at 919-515- 5218, at hhuang11@ncsu.edu, or to 4402D Engineering Building III, Raleigh, NC, 27695.

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_____
Email:
Ph No:
Today's Date _____

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

Thank you for your consideration.

BROAD CONSENT ADDENDUM

Title of Study where Broad Consent is Initially Sought: Improving Balance and Energetics of Walking using a Hip Exoskeleton **(eIRB # 24671)**
Principal Investigator(s): Varun Nalam (vnalam@ncsu.edu) and He Huang **(**919-515- 5218 and hhuang11@ncsu.edu)
Funding Source: None
NC State Faculty Point of Contact: He Huang **(**919-515- 5218 and hhuang11@ncsu.edu)
Collaborating Researchers: Qiang Zhang (qzhang25@ncsu.edu); Wentao Liu (wliu29@ncsu.edu) Ming Liu (mliu10@ncsu.edu); Abbas Alili (aalili@ncsu.edu); Michael Lewek (michael_lewek@med.unc.edu)

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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 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.

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 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 Improving Balance and Energetics of Walking using a Hip Exoskeleton 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 Improving Balance and Energetics of Walking using a Hip Exoskeleton 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 post-doctoral researcher, Varun Nalam, at vnalam@ncsu.edu and 919-

948-9696. You can also contact the faculty advisor for this research, Dr. He (Helen) Huang, at hhuang11@ncsu.edu and 919-515- 5218.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 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 the post-doctoral researcher, Varun Nalam, at vnalam@ncsu.edu and 919-948-9696. You can also contact the faculty advisor for this research, Dr. He (Helen) Huang, at hhuang11@ncsu.edu and 919-515- 5218

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

NC STATE UNIVERSITY

Informed Consent for Participation in Research

Consent Form for participants affected by stroke

Title of Study: Improving Balance and Energetics of Walking Using a Hip Exoskeleton **(eIRB # 24671)**

Principal Investigator(s): Dr. Varun Nalam (vnalam@ncsu.edu) and Dr. He Huang **(**919-515-5218 and hhuang11@ncsu.edu)
Funding Source: None
NC State Faculty Point of Contact: Dr. He Huang **(**919-515- 5218 and hhuang11@ncsu.edu)
Collaborating Researchers: Qiang Zhang (qzhang25@ncsu.edu); Wentao Liu (wliu29@ncsu.edu) Ming Liu (mliu10@ncsu.edu); Abbas Alili (aalili@ncsu.edu) ; Michael Lewek (michael_lewek@med.unc.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 demonstrate the effectiveness of a hip exoskeleton device to improve stability and reduce exertion in participants. We will do this by attaching a robotic hip exoskeleton on the pelvis of participants and using it to provide assistance during different tasks, like sit-to-stand, walking on a treadmill, level-ground walking, walking on a ramp, stairs climbing and descending, and so on. We will collect data on how your muscles move and react to the exercises that you will do as part of the research. In addition, a mask will be used for measuring metabolic cost. This mask will be attached on top of the surgical or N95 mask that you wear to comply with Covid protocols. The mask is disinfected and sanitized after every use. Apart from the robotic device, no other electrical simulation would be applied during the experiment.

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 research may lead to better balance and walking assistance in the paretic stroke community. You may not want to participate in this research because the related tasks may lead to fatigue and discomfort for some stroke patients due to walking for a longer time. Further, you may experience tripping while walking even though falling over is prevented using a regulatory safety harness. Finally, wearing a mask on the face might cause some discomfort along with additional discomfort and possible irritation when sensors are stuck to your skin.

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(s) 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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The purpose of the study is to evaluate and validate different control approaches of a powered hip exoskeleton for improving balance and reducing exertion during walking for people without any neurological disorders and for people affected by paretic stroke.

How many people will be in the study?

There will be approximately 100 participants in this study, but only 20 participants in the stroke group.

Am I eligible to be a participant 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:

- Between 18 and 64 years old
- Live in the United States
- Able to understand study requirements and sign an informed consent
- You have weakness on one side of your body due to a stroke within the past 6 months
- Your doctor can confirm that you had a stroke within the past 6 months
- You can walk without any assistance for at least 6 minutes and 1000 feet (a little less than a quarter mile)
- You can walk at a speed of 1 mile per hour
- You have normal or corrected-to-normal vision and hearing
- Capable of safely stepping on stairs without an Ankle Foot Orthoses but may use canes as needed

You cannot participate in this study if you do meet the inclusion criteria above or you:

- Cannot follow instructions or provide feedback due to cognitive, spatial awareness, and/or language limitations
- Are pregnant
- Cannot walk without an ankle-foot brace or a therapist's assistance
- Cannot walk or balance without help of a tool, such as a walker or cane
- Have vision, balance or reaching issues unrelated to stroke
- Use a electronically controlled medical device, such as a pacemaker, implanted defibrillator, or drug pump
- Have numbness, tingling or pain in any part of your body
- Have any skin related allergies or irritation to adhesives
- Have blood circulation, heart, metabolic, or cognitive disorders, including but not limited to:
    - Peripheral vascular disease
    - Pitting edema
    - Heart disease
    - Diabetes (uncontrolled)
    - Seizures

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 5 visits. Each visit will be up to 4 hours long, with 3 hours of that time engaged in physical movement. You will provide some demographic information before your first visit and after you pass the initial screening. The study does not cover any fee that your doctor might charge you to fill out the form.

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Before every visit, you will need to pass an online COVID-19 screening that is taken before you arrive.

During each visit, you will:

1. Be asked to walk normally without wearing any devices and equipment
2. Place and wear sensors, tape, and reflective markers on your lower legs and/or torso. The sensors will measure your muscle activity, the tape will make sure the sensors stay in place, and the reflective markers will help us record how your body moves during the lab visit.
3. The following sensors will be attached for the study. Wearing shorts is recommended to simplify the process of adding sensors.
    a. Muscle activity sensors: **Number:** 7 per limb. **Placement**: One on the lower hip, two in the back of the lower thigh, two in the front of the lower thigh, one on the shin and one on the calf. The area will be cleaned by an alcohol prep pad before attaching the sensor.
    b. Movement measurement sensors: **Number:** 7 in total. **Placement:** One on the lower back, one on each thigh, shank and foot.
    c. Movement measurement markers: **Number:** 22 in total. **Placement:** Two on the lower abdomen, two on the lower back, three on each thigh, shank and foot.
    d. Oxygen usage sensor: The sensor is worn like a mask which has a 2-inch tube. It measures the oxygen being breathed in and out to estimate how much oxygen is used. It does not obstruct any air flow.
4. You will also be asked to wear a robotic hip exoskeleton. The hip exoskeleton is a robotic device that you wear like a backpack and strap to your waist and thighs. The device has motors in parallel with your hips and applies a force on your thighs to help you perform tasks. The device weight slightly under 5 pounds, and you will have to wear it during walking.
5. While wearing the exoskeleton, sensors, tape, and reflective markers, you will:
    a. Learn how to walk wearing all of the devices and equipment
    b. While wearing the devices and equipment, you will perform activities of daily life, including:
        i. Walking on level ground
        ii. Walking on a treadmill
        iii. Walking on a ramp
        iv. Move from sitting to standing
        v. Move from standing to sitting
        vi. Climbing stairs
        vii. Descending down stairs
6. The exoskeleton will provide additional force during each task to help you do them with more ease and will learn the right amount of force to apply to help you perform the task.
7. You will perform the tasks for no more than 3-5 minutes each trial for a total of 10 trials with sufficient rest between trials.

The following procedures are experimental: We will be using a novel robotic hip exoskeleton device to develop optimal assistance control to help you perform various daily activities. The device is attached to your upper body like a backpack and is also strapped across each of your thighs independently. The device is developed at the lab as a prototype and is being evaluated for efficacy. To apply the assistance, the robotic hip exoskeleton device is connected to a DC power supply of 24 volts. The

supply is provided with shutoff and fuses to prevent excess voltage or current. So, any possibility of electric shock is minimal. Further, the force applied by the motors is also limited by the power supply so the risk of injury is minimized.

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 about 20 hours, which includes 5 visits to our lab (4 hours for each visit) over an 8-week period.

Recording and images

If you want to participate in this research, you must agree to be photographed and video recorded. If you do not agree to be photographed and video recorded, you cannot participate in this research. Additionally, we record your motion using reflective markers. The motion recording cameras can only see reflective markers and cannot be used to identify you. If you do not agree to be motion recorded, you cannot participate in this research. Video will be taken of your torso and lower limbs and will not include your face. Any identifiers, such as tattoos and birth markers, will be removed or blacked out from video and photo if they are captured before they are used for publication, presentation, and (with your consent) future research purposes.

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. 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 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. There is likely skin irritation due to the use of self-adhesive surface electrodes and/or small motor vibrators on the skin. However, this will be minimized by cleaning the skin before and after the experimental procedure. If the skin is irritated, the electrodes will be immediately removed, and the study will be terminated.
3. Although electrical motors are used for the powered hip exoskeleton, we do not anticipate any safety-related issues with this protocol. The two main risks are that the motor applies a force to the hip causing discomfort and injury, and the possibility of electric shock. The permitted current and voltage is limited by the power supply, which prevents any unreasonable application of force and an emergency shut off is implemented to minimize both risks.
4. You may fall during the experimental procedure. Although the consequence of fall is very high, we minimize the risk by providing additional protections. All the experimental procedures will be conducted under the coverage of a railing system designed to protect you from fall. During

the task, in which the railing system could not provide full protection, such as stairs and sit-to-stand, additional rails or walkers will be provided.

5. You may experience fatigue during the experimental procedure. Although the chance is low, you may experience minor fatigue and muscle pain. To prevent related risks, rest time is provided between trials and you can stop anytime you feel discomfort or for any reason.

There are no direct benefits to your participation in the research. The indirect benefits are to help stroke survivor community to improve balance and reduce exertion during multiple locomotion tasks.

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. He (Helen) Huang at 919-515- 5218, at hhuang11@ncsu.edu, or to 4402D 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 data from their data set, securely destroy your data, and prevent future uses of your data for research purposes wherever possible. This is possible in some, 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 that we have 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, NSF) 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, re-identifiable, and identifiable.

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. This will be most of the data we publish, as we plan to aggregate the findings into groups of 3 or more people, so it would be hard to know who an individual participant is.

Re-identifiable. Re-identifiable data is information we can 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. In this research, the re-identifiable data is the images and videos made during the lab visits. While we will crop out your face and blur identifying details such as tattoos and jewelry, we

cannot promise that your identity won't ever be figured out. This means that others may be able to re-identify from the information reported from this research.

Identifiable. Identifiable data is information you 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 information that are shared with us and other people. For the purposes of this research, the identifiable data that will be shared about you is your name, email, phone number with researchers for the purposes of compensation and communication to set up the study.

Future use of your 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. Your re-identifiable and identifiable information will not be kept or shared for future research by anyone.

Compensation

For your participation in this study, you will receive $15/hour per visit. The payment will be made through bank debit card. If you do not have a bank account, we will arrange gift card payment. Less than half hour will be counted as half hour; more than half hour, but less than one hour, will be counted as an hour.

If you withdraw from the study prior to its completion, you will be paid for the study duration in which you participated.

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.

What if you are an NCSU student?

As a part of the general population, you may participate in the research while under no obligation to. 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?

As a part of the general population, you may participate in the research while under no obligation to. 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.

Research collaborations

This research project is a cooperative effort between the following entities: North Carolina State University and University of North Carolina Chapel Hill.

Inventions and patents

He Huang is an inventor of the hip exoskeleton that is part of this research in which it is being used to assists locomotion. He Huang, Ming Liu, and Varun Nalam are also a part owners of Avex Motion to

whom the patent for hip exoskeleton has been licensed. If the technology is licensed at NC State University, a ICF disclosure in Sophia (the Office of Research Commercialization database at the University) must state that the University and the inventor may benefit from the invention. If this patent or approach is successful at some point in the future, NC State University and He Huang may receive financial benefits. If you would like more information, please ask the researcher(s) listed at the top of this form.

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. He (Helen) Huang at 919-515- 5218, at hhuang11@ncsu.edu, or to 4402D Engineering Building III, Raleigh, NC, 27695.

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_____
Email:
Ph No:
Today's Date _____

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

Thank you for your consideration.

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BROAD CONSENT ADDENDUM

Title of Study where Broad Consent is Initially Sought: Improving Balance and Energetics of Walking using a Hip Exoskeleton **(eIRB # 24671)**
Principal Investigator(s): Varun Nalam (vnalam@ncsu.edu) and He Huang **(**919-515- 5218 and hhuang11@ncsu.edu)
Funding Source: None
NC State Faculty Point of Contact: He Huang **(**919-515- 5218 and hhuang11@ncsu.edu)
Collaborating Researchers; Qiang Zhang (qzhang25@ncsu.edu); Wentao Liu (wliu29@ncsu.edu) Ming Liu (mliu10@ncsu.edu); Abbas Alili (aalili@ncsu.edu) ;Michael Lewek(michael_lewek@med.unc.edu)

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 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.

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.

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You will not personally benefit from saying “yes” in this form. Saying “yes” in this form is not a condition of participating in the Improving Balance and Energetics of Walking using a Hip Exoskeleton 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 Improving Balance and Energetics of Walking using a Hip Exoskeleton 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 post-doctoral researcher, Varun Nalam, at vnalam@ncsu.edu and 919-948-9696. You can also contact the faculty advisor for this research, Dr. He (Helen) Huang, at hhuang11@ncsu.edu and 919-515- 5218.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 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 the post-doctoral researcher, Varun Nalam, at vnalam@ncsu.edu and 919-948-9696. You can also contact the faculty advisor for this research, Dr. He (Helen) Huang, at hhuang11@ncsu.edu and 919-515- 5218

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

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☐ **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