Permission to Take Part in a Human Research Study

Title of Research Study: **Soft Exosuits for Functional Gait Recovery in Acute Stroke Rehabilitation**

Investigator: Arun Jayaraman, PT, PhD

Supported By: This research is supported by a grant from National Institute on Disability, Independent Living, and Rehabilitation Research.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you have had a stroke which has affected your ability to walk.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
This study will utilize soft exosuits, Rewalk Restore or a similar Wyss ankle exosuit, and/or a Wyss hip flexion exosuit which all act to assist you in regaining a normal walking pattern as prior to your stroke. The Rewalk Restore or similar Wyss ankle exosuit provide assistance at your ankle by bringing your foot up and down as you walk in the normal pattern while the Wyss hip flexion exosuit provides assistance at your hip by bringing it up. Which device you end up using will be based on where you have more difficulty with your walking, either at your ankle and/or hip.

You may not necessarily directly benefit from participating in this research but this study will assist researchers developing interventions, such as using an exosuit, to treat individuals who have had a recent stroke. The Rewalk Restore is approved by the US Food and Drug Administration to treat mobility issues due to stroke while the Wyss ankle exosuit and Wyss hip flexion exosuit is not approved.

There are two aims of this study. **We will review the procedures involved in AIM 1 first and then discuss AIM 2.**

If you participate in AIM 1 of the study, we will be further identifying which patients will be able to use these devices and developing the controllers so that the devices can work with a greater range of patients following stroke. During this part of the study we will also be developing a progression strategy based on what is difficult with your walking.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 8 weeks if you are in AIM 1.

- For AIM 1, you will be asked to attend up to 3 testings sessions, and up to 8 tuning and training visits using the exosuits. There are 2 additional buffer sessions that will be used if needed to complete testing or tuning in the event of incomplete data collection, scheduling limitations, device failure, etc

For AIM 1 , you will only wear the exosuit during training sessions.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

Your participation in this study may involve the following risks:

- Because the device is designed to fit snugly on your affected leg, it is possible that you may experience discomforts on your leg including but not limited to: skin redness or irritation, numbness, swelling, or tingling. Rare risks related to the device include shock.
- If you experience pain or discomfort at any time during the study, let the researcher know so that the issue can be addressed. While walking and standing, there is a risk of tripping or falling. For your safety, a member of the study team and a licensed physical therapist will remain close to you. If necessary, an overhead harness system will be used to ensure your safety. Additional risks related to gait training include the potential to become fatigued, have muscle or joint soreness, minor muscle cramps or become short of breath. Less likely risks related to gait training include muscle strain/tear, dizziness, chest pain, an irregular heart rate, fainting, or an injury from a fall. To minimize this risk, you will be allowed to take rest breaks at any time.
- There is a risk that the exosuits may not work properly. This risk is minimized by having trained staff who are experienced in the devices with you during all sessions. If this goes beyond the anticipated time for the session, we will reschedule the session.
- There also may be risks and discomforts that cannot be foreseen.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a better understanding of how exosuits can be utilized in acute stroke recovery to aid walking recovery.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. You can choose to stop being in this study at any time.

Instead of being in this research study, your choices may include: Not participating in this study.

The following applies to participants considering participation in AIM 2 of this study:

Why is this research being done?

If you participate in AIM 2 of the study, you are currently in participating in inpatient rehabilitation following a recent stroke. We want to see how the combination of the exosuits to your conventional physical therapy versus conventional physical therapy alone impacts the recovery of your walking ability.

How long will the research last and what will I need to do?

You will participate through the duration of your inpatient stay if you participate in AIM 2.

For AIM 2, you will participate in an in-person screen assessment, a baseline testing visit, and a post evaluation prior to discharge from inpatient rehabilitation. There are 2 additional buffer sessions that will be used in the case there is incomplete data collection, or scheduling limitations. You may utilize the exosuit in your physical therapy sessions throughout your inpatient stay if you are randomized into this group otherwise you will continue with your typical physical therapy sessions.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have a(n) equal chance of being given either treatment – either training with the exosuit or without the exosuit during physical therapy sessions during your inpatient stay.

For AIM 2, you will only wear the exosuit during training or therapy sessions.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

Your participation in this study may involve the following risks:

- Because the device is designed to fit snugly on your affected leg, it is possible that you may experience discomforts on your leg including but not limited to: skin redness or irritation, numbness, swelling, or tingling. Rare risks related to the device include shock.
- If you experience pain or discomfort at any time during the study, let the researcher know so that the issue can be addressed. While walking and standing, there is a risk of tripping or falling. For your safety, a member of the study team and a licensed physical therapist will remain close to you. If necessary, an overhead harness system will be used to ensure your safety. Additional risks related to gait training include the potential to become fatigued, have muscle or joint soreness, minor muscle cramps or become short of breath. Less likely risks related to gait training include muscle strain/tear, dizziness, chest pain, an irregular heart rate, fainting, or an injury from a fall. To minimize this risk, you will be allowed to take rest breaks at any time.
- There is a risk that the exosuits may not work properly. This risk is minimized by having trained staff who are experienced in the devices with you during all sessions. If this goes beyond the anticipated time for the session, we will stop using the exosuit during your therapy session, or reschedule the testing session and utilize a buffer session.
- There also may be risks and discomforts that cannot be foreseen.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a better understanding of how exosuits can be utilized in acute stroke recovery to aid walking recovery.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. You can choose to stop being in this study at any time.

Instead of being in this research study, your choices may include:

Not participating in this study or if you are currently undergoing inpatient rehabilitation, you can continue your normal rehabilitation.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Arun Jayaraman, PT, PhD, the person in charge of this research study. He can be reached at 312-238-6875 during business hours Monday to Friday 9am-5pm. For problems arising during the evenings or weekends, you may call 352-246-1166.

You may also call Kristine Buchler at 312-238-7114 with questions about this research study from Monday-Friday 9 am to 5 pm.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 80 people here will be in this research study out of 80 people in the entire study nationally.

What happens if I say "Yes, I want to be in this research"?

AIM 1:

	Duration	Completed on this Visit
Screen – phone or in person Consent	Up to 30 minutes	-Explain study -Answer participant questions

		-Collection of background participant information – medical history, stroke history, complete cognition screen -Consent -Obtain medical clearance from your physician prior to next visit
Testing session - up to 3 visits	Up to 3 hours	10 meter walk test with GAITRite 2 minute walk test Manual Muscle Test of the legs Range of motion of the legs Modified Ashworth Scale of the legs Burke Lateropulsion Scale
Tuning and Training Visits – up to 8 visits	Up to 2 hours	Walking and tuning in exosuit up to 60 minutes on treadmill, overground and on the stairs with rest breaks as needed, including active assist and walking with device not assisting you for comparison. -10 meter walk test -2 minute walk test

If you decide not to participate in this study, information including medical history and stroke history collected during the primary screening will be securely destroyed.

AIM 2:

	Duration	Completed on this Visit
Screen – in person	Up to 30 minutes	-Explain study -Answer participant questions -Collection of background participant information – medical history, stroke history -Ensure participant meets eligibility criteria for the study and is able to fit within device specifications -Consent -Obtain medical clearance from your inpatient physician prior to next visit
Baseline – Visit 1	Up to 4 hours	10 meter walk test Gait mechanics assessment 6 minute walk test with Cosmed 2 minute walk test Fugl-Meyer 5x Sit to Stand Timed Stair Climb Test Berg Balance Scale Functional Gait Assessment Functional Independence Measure PHQ-9 Manual Muscle Test of the legs Range of motion of the legs

		Modified Ashworth Scale of the legs
Randomize into Exosuit or Non-Exosuit Group		
Throughout Inpatient Stay: Physical Therapy Sessions	30-90 minutes	If in an exosuit group, your physical therapy sessions will occur using the exosuit
Post Evaluation – Visit 10	Up to 4 hours	Same assessments as visit 1

Testing Session – Additional Test Details:

AIM 1:

- 10 meter walk test: is a test of your walking speed at your normal and fast pace
- GAITRite: this is a specialized mat which can identify and mark your steps while walking. The system provides information about step time, step length, speed etc.
- Gait Mechanics Assessment: additional metrics to capture how you are walking including motion capture which involves using multiple cameras around you and sensors on your body to capture your movement or inertial measurement units which collect information about acceleration, orientation of your body, and velocity.
- 2 Minute walk test: is a test of your walking endurance where you walk as far as you can in 2 minutes
- Burke Lateropulsion Scale: measure of pushing behavior in various positions
- Modified Ashworth Scale: measure of spasticity in the legs, particularly at the hips and knees
- Manual Muscle Test: testing the strength of the legs, particularly the hips and knees.
- Range of motion: a test of the amount of motion in the legs, measured at the hips and knees.

AIM 2:

- 6 minute walk test: is a test of your walking endurance where you walk as far as you can in 6 minutes
- Cosmed: is a system used to measure energy expenditure and how efficiently you can use oxygen as you walk as you complete the 6 minute walk test. It involves wearing a mask over your nose and mouth to capture this information.
- 2 Minute walk test: is a test of your walking endurance where you walk as far as you can in 2 minutes
- Fugl-Meyer Assessment of Motor Recovery: assesses lower body movement capability
- 5x sit to stand: tests how quickly you can stand up and sit down from a chair.
- Berg Balance Scale: is a test of your standing balance without an assistive device.
- Functional Gait Assessment: is a test of your moving balance.
- Timed Stair Climb Test: is a test of how quickly you can go up and down a set of stairs.
- Functional Independence Measure: measure the level of independence for various tasks such as eating, walking, transfers, stairs etc.
- PHQ-9: Patient Health Questionaire, is a 9 question screen for depression.
- Manual Muscle Test: testing the strength of the legs, particularly the hips, knees, and ankles.
- Range of motion: a test of the amount of motion in the legs, measured at the hips, knees and ankles.

Modified Ashworth Scale: measure of spasticity in the legs, particularly at the hips, knees, and ankles.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Attend all scheduled visits
- Communicate with the research staff if you have any questions, discomfort or need to rest during the study.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can remove you from the study.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, your class standing (for students enrolled in a class at NU), or your present or future employment (for employees at NU or its affiliates).

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data

Detailed Risks: Is there any way being in this study could be bad for me?

This research may hurt you in the following ways:

- The risk of falling: There is a risk of falling during testing and training. The risk of falling will be reduced by supervising you during training and testing by a research team member trained in all testing procedures and device use. You will be educated in the safe use of the device. The risk will be similar to that of any clinical physical therapy session.
- Significant change in vitals: including blood pressure, heart rate, oxygenation related to exertion during physical activity. This risk will be reduced by taking your vitals prior to each session, as well as asking how you feel during sessions. We will take your vitals as needed during and after sessions as well.
- Risk of discomfort, pain, pressure, skin irritation, blistering, rubbing or chaffing from wearing the exoskeleton which has the potential to lead to skin breakdown or abrasions. This risk will be minimized by having research personnel perform thorough skin check before and after each device use, as well as education in monitoring skin integrity. The device fit will be regularly monitored by research personnel. Adjustments to and additional padding will be added as needed to decrease the risk of skin breakdown.
- Device malfunction. The risk will be minimized by regular monitoring of the device by research personnel.
- Risk of fatigue and muscle soreness. You may have increased joint pain or muscle soreness during screening, testing, and training activities due to increased walking. You can stop and rest if you get fatigued. Settings on the exosuit can also be adjusted if you are experiencing pain and discomfort.
- There is a risk that the exosuit may not work properly. This risk is minimized by having trained staff who are experienced with the devices with you during all sessions.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include: a better understanding of how exosuits can be utilized in acute stroke recovery to aid walking recovery.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, or our collaborating institution, Harvard University.

If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

The sponsor, collaborating institution, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Per a specific aggreement, collaborators will have access to training session logs, outcome measures assessed by the research team, and non-identifiable person health information including:

- Gender
- Age
- Weight
- Height
- Time since stroke

You will have the opportunity to indicate whether you would like to have your video/photo data shared with collaborators or used for publications, presentations or training purposes. Because this device is designed for the leg, we will do our best to exclude your face.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include inability to comply with study procedures, or concerns for safe use and tolerance for the exosuits.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you $20-50 per completed session for your time and effort.

You will be paid $20 for each in-person screen, training/tuning session, buffer session (if used) and $40 for each testing session that you attend for AIM 1 (up to total of $340).

For AIM 2, you will be paid $50 for each evaluation session and $20 for each buffer session (if used) (up to total of $140). These funds are provided to help support you with time and travel associated with your participation.

The Shirley Ryan AbilityLab will issue you a ClinCard, which is a specially designed debit card for clinical research. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card. The funds will be available within 1 day after being loaded and can be used at your discretion.

You will be issued one card for the duration of your participation. If your card is lost or stolen, please call (866) 952-3795 or ask a coordinator for a replacement ClinCard.

Fees are incurred if used at an ATM (fees vary by location). However, if the card is used for in-store or online purchases via credit or debit, there are no associated fees and no expiration date.

Please be advised: Inactivity on the card for more than 3 months will incur a monthly fee. However, as long as there is activity on the card within 3 months (funds are added or a transaction is completed), the month period will reset and no monthly fee will be assessed.

If you do incur a monthly fee, please contact Greenphire Support at the number on the back of your card and they will reverse the fee. See "Tips for Using the Attached ClinCard" for more information.

The Finance Department at the Shirley Ryan AbilityLab will be provided with your information, including your Social Security Number, in order to issue payment for your study participation. Study payments are considered taxable income and reportable to the Internal Revenue Service (IRS). An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

You may be given access to new inventions that are being developed by the investigator, the study sponsor, or other people involved in the study. Certain laws can make it harder to obtain legal protection for a new invention shared with a study participant, unless the study participant agrees to keep information about the invention confidential. You agree to keep confidential information you may receive about new inventions, such as new drugs, new devices, or new methods.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study devices
- Gender
- Age
- Weight
- Height
- Type of stroke
- Time since stroke

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office, as well as collaborating institution, Harvard University].

The following entities may receive your health information:

- Authorized members of the Northwestern University and the Shirley Ryan AbilityLab workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study, including the collaborating institution
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Arun Jayaraman, PT, PhD
Institution: Shirley Ryan AbilityLab

Department: Max Nader Center for Rehabilitation Technologies and Outcomes, Center for Bionic Medicine
Address: 355 E. Erie Street, Suite 1402, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Permission to Take Part in a Human Research Study

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____

Signature of Witness to Consent Process Date

_____

Printed Name of Person Witnessing Consent Process