Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: Wearable Sensor Platform to Monitor Stroke Recovery: A Clinical Exploratory Trial

Investigator: Arun Jayaraman, PT, PhD

Supported By: This research is supported by The Shirley Ryan AbilityLab and NIDILRR (National Institute Disability, Independent Living, and Rehabilitation Research)

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 a had a stroke. Or, you may be asked to be a part of a healthy "control" group without any known significant health problems.

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.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can contact the Primary Investigator, Arun Jayaraman, at (312) 238-6875 or the lab manager, Sara Prokup, at (312) 238-1355 during business hours Monday to Friday, 9:00 a.m. to 5:00 p.m.

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.

Why is this research being done?

The purpose of this study is to test body-worn sensor technology, that can help clinicians and therapists track how well someone is recovering from a stroke while they are going through rehabilitation in a hospital. The ability to continuously monitor how well someone is functioning and moving with these sensors may help to guide the rehabilitation process to make it more effective for patients.

You should not participate in this study if you are under the age of 18, if you are pregnant, or have any powered, implanted cardiac devices for monitoring or supporting heart function (i.e. pacemaker, defibrillator, or LVAD).

How long will the research last?

We expect that you will participate in this research study for up to 5 laboratory visits expected to last 2-3 hours, taking place at the Shirley Ryan AbilityLab.

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How many people will be studied?
We expect about 400 people who have experienced a stroke will be in this research study, as well as about 100 people who are a part of the control group.

What happens if I say "*Yes, I want to be in this research*"?
You will undergo up to three different types of assessments while wearing the body-worn sensors during up to three laboratory visits. These assessments will be clinical, swallowing/speech, and exercise assessments.

The sensors will be placed with Velcro straps or on the skin using adhesive stickers that minimize friction, with additional support of medical dressings as needed. All assessments will be performed under the supervision of trained research personnel. You will be given rest breaks as needed between tests to minimize fatigue. Therapist assistance and body-weight support will be provided as needed.

1. Clinical Assessment:
Sensors will be worn with various common clinical tests that will be performed. These may include:

1. Modified Ashworth Scale (MAS)
2. 10-Meter Walk Test (10MWT)
3. 6-Minute Walk Test with or without VO2 analysis (6MWT)
4. Berg Balance Scale (BBS)
5. Functional Gait Assessment (FGA)
6. Quality Indicators (QI)
7. Timed Up and Go (TUG)
8. Manual Muscle Test (MMT)
9. Action Research Arm Test (ARAT)
10. Gait analysis using GaitRite: slow, self-selected, and/or fast walking speeds

- **Modified Ashworth Scale (MAS):** The MAS is a 6-point scale used to measure severity of muscle stiffness or tightness by testing resistance to stretch of your muscles around a joint with varying degrees of speed. You will be asked to lay down and allow the therapist to move your limbs and assess for stiffness or tightness.
- **10-Meter Walk Test (10MWT):** The 10MWT measures the amount of time it takes to walk 10 meters. Time will be recorded using a stopwatch. The test will be recorded 3 times at your normal self-selected pace, 3 times at a faster pace, and 3 times at a slower pace with adequate rest in between. Results will be averaged from each set of 3 trials. Photographs or videos may be recorded during the test to aid in data analysis
- **6-Minute Walk Test with VO2 analysis (6MWT):** The 6MWT measures the distance a subject can walk indoors on a flat, hard surface in a period of 6 minutes, using assistive devices, as necessary. You are allowed to take rest breaks, however a timer will continue to run. A physical therapist will walk with you to ensure safety and assist as needed. A researcher will measure how many feet you walk during the 6-minute timeframe. You will also wear a mask over your mouth and nose during the test, which

will be attached to a small box worn over your shoulder. You will breathe through this mask so that the amount of oxygen you use during the test can be measured.

- **Berg Balance Scale (BBS):** The BBS is a 14-item test. It measures how well you can balance while performing movements in sitting and standing (such as sitting, standing, transitioning from sitting to standing, standing on one foot, retrieving an object from the floor.) A physical therapist will ensure your safety and assist as needed during the test.
- **Functional Gait Assessment (FGA)**: The FGA is a 10-item test for assessing postural stability during various walking tasks. Walking tasks include speed changes, head turns, stepping over obstacles, backwards, and stair climbing. Each item is scored based on the performance between 0-4.
- **Timed Up and Go (TUG):** The TUG is a timed test that involves the participant rising from a chair, walking three meters, turning around, walking back to the chair, and sitting down. Photographs or videos may be recorded during the test to aid in data analysis
- **Quality Indicator (QI)**: QI will be done on admission and discharge (mean stay 23 days for stroke patients). The QI evaluates how much assistance is needed to perform certain activities of daily living. Each item is scored ranging from total assistance to total independence. Items include eating, grooming, bathing, dressing, toileting, bladder/bowel management, transfers, locomotion and stairs, comprehension, etc.
- **Manual Muscle Test (MMT):** The MMT is a standardized assessment to measure muscle strength. The therapist will use one hand to apply resistance or activate the muscle or tendon for contraction while the other hand stabilizes the body part being tested. The test will be repeated on all muscle groups required.
- **Action Research Arm Test (ARAT):** The ARAT is a 19-item test. It is used to test arm function and is divided into four subtests: grasp, grip, pinch, and gross movement. You will be asked to pick up various items (wooden block, ball, stone, tube, marble, ball bearing) and will be scored on your ability to do so.
- **Gait analysis:** You will be asked to walk approximately 13 feet on top of a mat that has sensors inside of it. The sensors in the mat will that generate a picture of your foot steps on a computer. You may use your assistive device while walking. A physical therapist will walk with you to ensure your safety and assist as needed during the test. You will perform 3-5 trials at different walking speeds (slow, self-selected, and/or fast). Photographs or videos may be recorded during the test to aid in data analysis

2. Swallowing/Speech Assessment:
You will wear the sensor(s) during eating to capture swallowing, throat clearing, coughing, wheezing, or gurgling noises, and during a standardized speech and language test.

3. Exercise Assessment:
The Exercise Assessment will involve walking on a treadmill for up to 45 minutes. You may also perform exercises of walking up and down stairs, cycling (lower limbs), and balance for up to 10 minutes each. All activities will be perfomed at a comfortable pace

with opportunities to rest as needed. Sensors can measure your vital signs, sweat, as well as movement and muscle activity in the upper and lower limbs.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to: participate in all scheduled sessions and notify the research team of any changes in your health.

What happens if I do not want to be in this research?
You are not required to be in this research. If you chose not to be involved, then you will continue to undergo your regular rehabilitation care while in the hospital.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time and it will not be held against you.

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.

Information collected prior to the study discontinuation by a participant may still be used by the research team.

What are the risks of being in this study? Is there any way being in this study could be bad for me?
There is a risk of muscle soreness due to increased physical activity during testing sessions. All subjects will work with trained researchers and clinicians. Adequate rest will be given and subjects will be monitored for verbal or visual signs of fatigue or discomfort. There is a risk of falling during clinical and exercise assessments. The risk of falling will be reduced by having each participant supervised during training and testing by a clinician or researcher trained in all testing procedures. During these assessments, the participant will use a gait belt for safety. The risk is similar to that during any clinical inpatient/outpatient therapy session.

There is a risk of irritation to the skin from wearing the sensors. This risk will be reduced by minimized by excluding people who have a known allergy and discontinued use if skin irritation occurs.

Risks associated with swallowing and speech activities are the same as those associated with routine standard of care. You may experience difficulties swallowing or choking during mealtimes. There may also be frustration if speech tasks are deemed too difficult. Trained therapists will be present for all swallow/speech tasks, and you will be given frequent rest breaks as needed.

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?
There will likely be no direct benefit by participating in this research study. The long-term goal of this research is to improve the ability to measure symptoms of stroke and look at the

impact of new therapeutic interventions during the inpatient stay. This benefit could lead to better treatments in the future.

What happens to the information collected for the research?

The data collected in this study includes the biometric data collected by the sensor devices, as well as information about your height, weight, age, gender, and medical history. Shirley Ryan AbilityLab will take appropriate measures to protect your information. Keeping the confidentiality of all data collected through this study is paramount and measures are taken to ensure the privacy of the participants.

Upon completion of data collection phase of the study, all de-identified data will be transferred to internal servers and only accessible to research staff. This includes the John Rogers research group at Northwestern University, who developed some of the sensor technology used in this study.

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.

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, 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), 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.

The data collected in this study will also be accessible to the John Rogers research group at Northwestern University, who developed some of the sensor technology used in this study.

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 a medical event or complication that may alter the inclusion/exclusion criteria, or which limits the patient from safely completing the remainder of the study, or at the discretion of the PI.

What else do I need to know?

Please be adviced that these sensors have not been tested on the following groups: pregnant women, individuals with powered, implanted cardiac devices for monitoring or supporting heart function (i.e. pacemaker, defibrillator, or LVAD), and individuals below 18 years of age.

If you become ill or get 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.

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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.

You will be paid $40 for each session that you attend. 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:

- Pertinent information in a medical record related to your stroke
- 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 medication or drugs
- Records about study devices

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Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people 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 will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is necessary for review by such parties or is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office].

- 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 (a committee which is responsible for the ethical oversight of the study).
- Clinical affiliates, including but not limited the Shirley Ryan AbilityLab, 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.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly.
- Registries or other research-related databases such as the C-STAR Movement Database

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. Also, Federal law/42 CFR Part 2 prohibits unauthorized disclosure of these records.

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
Institution: Shirley Ryan AbilityLab
Department: Center for Bionic Medicine
Address: 355 E Erie St, #1401, 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.

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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.

Please initial one of the following to indicate your choice:

_____ (initial) I **agree** to have photographs and videos taken to aid with data analysis or for use in education, scientific publications or presentations **with my face included.**

_____ (initial) I **agree** to have photographs and videos taken to aid with data analysis or for use in education, scientific publications or presentations **without my face included.**

_____ (initial) I **do not agree** to have photographs and videos during my study participation.

_____ (initial) The researchers **may** use the data that is collected through my participation in this study to upload to a public database that researchers and clinicians may use for purposes of data analysis.

_____(initial) I **agree** the researcher may contact me in the future to see whether I am interested in participating in other research studies.

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	Date
_____	_____
Signature of Person Obtaining Consent	Date
_____	_____
Printed Name of Person Obtaining Consent	Date

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If participant is physically unable to sign, please have a witness sign below:
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	Date