Title: Assessment of a Microprocessor Ankle for Low Mobility Individuals

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Protocol and Statistical Analysis Plan

1. Study Aim, Background and Design

Over 600,000 people in the US had a major lower limb amputation in 2005, and that number is expected to double by 2050 [1]. Within this population, up to 44% of individuals are classified as low mobility prosthetic users or below (described subsequently) [2]. Major lower limb amputations are defined as those with at least an ankle amputation, and as such, all these individuals require at least an ankle prosthesis to restore ambulatory mobility.

The Centers for Medicare and Medicaid Services (CMS) defines a range of Medicare Functional Classification Levels (MFCLs) through the Healthcare Common Procedure Coding System (HCPCS) to categorize mobility levels for individuals with lower limb amputation (ILLAs) [3]. These levels, which range from zero to four, are referred to as K-levels. The HCPCS also includes codes for prosthetic and orthotic devices, prefixed with the letter 'L', and known as L-codes. This classification aids in medical coding for reimbursement, as different K-levels qualify for different L-codes. Although intended for Medicare use, private insurers use these guidelines to determine whether to reimburse for services or devices, and how much to pay for them. Consequently, the devices for which an individual is deemed eligible are determined by their mobility level.

A critical distinction between mobility levels is the transition from K2 to K3. The distinguishing feature of the K3 mobility level is "the ability or potential for ambulation with variable cadence" [3]. An individual who qualifies as K3 is able to access a wider range of L-codes, and, in turn, more advanced devices. However, the nature of the prosthetic intervention affects the ease with which someone can vary their cadence. Furthermore, MPC prostheses have been shown not only to help K2 users transition to K3 [4], but also to improve safety measures [5, 6] that are equally, if not more, relevant to the K2 population.

Synchro Motion, LLC developed a novel MPC ankle that is based upon actuator technology originally from Vanderbilt University. Because of its unique actuation scheme, the prosthesis can behave as: (1) a lockable conformal damper, (2) a variable set-point spring, and (3) an actively repositionable joint. The investigators therefore refer to the device as the damping, stiffness, and repositioning (DSR) ankle. Compared to a fully powered prosthesis, the DSR ankle is small, lightweight, quiet, and runs for multiple days on a single charge.

The aim of this project is to conduct a preliminary investigation into the potential mobility, stability, and safety benefits of the DSR prosthetic ankle-foot for persons with amputation at a K2-level. Although the DSR ankle was originally developed for K3/K4 individuals with lower limb amputation (ILLAs), the investigators hypothesize that the DSR ankle may also benefit K2 ILLAs. The Center for Bionic Medicine (CBM) at the Shirley Ryan AbilityLab (SRALab) in Chicago and Synchro Motion have partnered in order to perform a pilot study to quantify the effectiveness of the proposed ankle as compared to a predicate non-MPC ankle in improving performance for K2 individuals with lower limb amputation.

2. Participant Population

The participant population consists of adults (aged between 18 and 89 years) who have a unilateral transtibial amputation and who are able to wear and use a prosthesis and who

currently use a passive, non-MPC prosthesis. All subjects are expected to be healthy individuals. The proposed study will require subjects to be fitted with the DSR ankle, using their own socket, and to receive training using both their own prosthesis and the DSR ankle. Subjects will be recruited from the prosthetics and orthotics clinic and physicians at the SRALab or through an SRALab registry listing individuals with amputations who are willing to participate in research. They may also include people who have previously taken part in research projects at the Center for Bionic Medicine (CBM) or SRALab. Subjects will undergo prosthetic fitting, training, and outcomes testing at the SRALab.

3. Study Procedures

Subjects will be recruited and provide informed consent before enrolling in this study. Once the subject has given written consent to participate, a clinician will interview the subjects and do an appropriate exam with respect to the amputated limb and their ability to use a prosthesis. Subjects will be examined to determine the range of motion and strength in all of their extremities including the amputated limb. We will obtain a brief medical history, indicating when their amputation was performed and what type of prosthesis and assistive device they use. Subjects will also undergo a brief physical exam to ensure they meet the inclusion criteria, and we will collect residual limb measurements and obtain subjects' weight and height.

The DSR ankle will be attached to the participant's own socket (participants will each have at least 2 visits for device fitting). For each ankle, subjects will receive approximately 4 training sessions over two weeks (1-2 per week), followed by a 3-4 assessment sessions. All training and testing will take place in the laboratory. After testing with the first device is complete, there will be a 2-week washout before training and testing on the second device.

No specimens will be obtained from subjects. We will obtain information from standard performance measures and patient-reported measures. All data will be collected at the SRALab.

4. Statistical Analysis Plan

This is a preliminary pilot study intended to gather the initial data necessary for proper statistical design and power calculations in a subsequent Phase II proposal. Because pilot data has not yet been collected on the target population, power calculations are not currently possible. Furthermore, since the number of subjects in this study is small, the statistical power from this study on its own is likely to be low, but it is hoped that the results will justify a Phase II study that is likely to achieve statistically significant results with a reasonable sample size.

5. Research Risks

The risks of the experimental part of the study are small.

- The largest risk is the risk of falling, which is a risk for all lower limb prosthesis users.
- Other risks include minor skin irritation, minor muscle soreness, and fatigue.

• There is some risk that subjects' identities may be revealed as a result of participating in this study.
• There are no other known social, legal, or other risks in these experiments.

6. Funding Sources

This work is funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development through a Phase I STTR award.

7. References

[1] Ziegler-Graham, K., MacKenzie, E.J., Ephraim, P.L., Travison, T.G., et al., Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050. *Arch. Phys. Med. Rehabil.* 2008, *89*, 422–429.
[2] Whiteside, S., Practice Analysis of Certified Practitioners in the Disciplines of Orthotics and Prosthetics. 2015.
[3] Lower Limb Prosthetic Workgroup Consensus Document. n.d.
[4] Hafner, B.J., Smith, D.G., Differences in function and safety between medicare functional classification level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control. *J. Rehabil. Res. Amp Dev.* 2009, *46*, 417–434.
[5] Hafner, B.J., Willingham, L.L., Buell, N.C., Allyn, K.J., et al., Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition From Mechanical to Microprocessor Control of the Prosthetic Knee. *Arch. Phys. Med. Rehabil.* 2007, *88*, 207–217.
[6] Kaufman, K.R., Bernhardt, K.A., Symms, K., Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees. *Clin. Biomech.* 2018, *58*, 116–122.
[7] Bullock, I.M., Zheng, J.Z., De La Rosa, S., Guertler, C., et al., Grasp frequency and usage in daily household and machine shop tasks. *IEEE Trans. Haptics* 2013, *6*, 296–308.

Permission to Take Part in a Human Research Study

Title of Research Study: Assessment of a Microprocessor Ankle for Low Mobility Individuals with Amputation: Phase I.

Principal Investigator: ***Arun Jayaraman, PT PhD***

Supported By: This research is supported by the National Institutes of Health and Shirley Ryan AbilityLab Max Nader Center for Rehabilitation Technologies and Outcomes 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 a below the knee amputation (amputation at the level of the lower leg) on one side, use a prosthetic foot for walking, and utilize your prosthesis as a K2 level walker. A K2 level ambulator is a person who has the ability or potential for ambulation with the ability to navigate low-level environmental barriers such as curbs, stairs, or uneven surfaces. This is typical of a limited community ambulator.

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 research is being done to conduct a preliminary investigation into a new prosthetic micro-processor controlled (MPC) ankle, called the Damping, Stiffness, and Repositioning (DSR) ankle. The DSR ankle is a new design to support a person while they walk on both even and uneven ground, as well as with bending the ankle for safe foot clearance while a person takes a step. In particular, in this study we are interested in seeing how this type of new prosthetic foot may benefit people who use their prosthesis as a K2-level ambulator.

The DSR ankle is currently an investigational device and not approved by the US Food and Drug Administration.

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

We expect that you will be in this research study for approximately 9 weeks, though additional visits may be required to complete all research activities. During the 9 weeks you will need to come into Shirley Ryan Ability lab for approximately 10-16 visits, with each visit lasting approximately 3 hours.

You will be asked to come into the research lab to train, fill out questionnaires and perform a series of walking and mobility tests, using both your own prosthetic ankle, and the DSR ankle. You will be trained in how to safely use the DSR ankle over 2-4 training sessions prior to doing the tests. You will not be taking the DSR ankle home for a home-trial.

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?

There are some risks of using the DSR ankle that are similar to the risks of using other prosthetic feet components. There are also risks associated with performing the training and the functional testing. These risks include skin irritation, muscle soreness, risk of falling, fatigue, and unforeseen risks that may occur due to device malfunctioning.
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 in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, this research may help scientists and researchers in the development of new prosthetic devices and technology.

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.

Your alternative to participating in this research study is to not participate.

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, you should call us promptly. Arun Jayaraman, PT, PhD is the person in charge of this research study. You can call him at 312-238-6875. You can also call Shenan Hoppe-Ludwig, CPO, at 312-238-5658 or Matt McGuire – PT, DPT at 312-238-3457 with questions about this research study during normal business hours Monday-Friday.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irbcompliance@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 10 people here will be in this research study.

What happens if I say "Yes, I want to be in this research"?
As a subject in the study, you will be asked to come to the Shirley Ryan AbilityLab (SRALab) Floor 11 research and clinical areas. Your participation in the study will last approximately 9 weeks.

Baseline Visits (1-2 visits): These visits are expected to last up to 3 hours each. The study will be explained to you. If you would like to take part in the study, you will sign this consent form and then be enrolled in the study. Once enrolled, a set of assessments or tests will be performed to ensure you are eligible to participate safely in the study. These assessments include:

- Vital signs (measurements of your heart rate, blood pressure, height, and weight.)
- Oxygen saturation measurements by briefly placing a small clip device over the tip of your fingers.
- Skin examination of both your lower extremities.
- Range of motion and strength testing of both your lower limbs at the hips and knees, and also at the ankle on your unaffected limb
- An evaluation of your clinical prescribed prosthetic limb and what you currently use for the various components (parts) of your prosthesis.
- You will be asked to rate the location and level of any pain you experience.
- You will perform the Amputee Mobility Predictor Assessment Tool (AMP) which is a series of tasks that tests your balance and mobility while in your prosthesis. A trained member of the research team will be next to you for safety.
- You will be asked to fill out a questionnaire that asks about your activity levels, and any goals that you may have regarding wearing your prosthesis.

If you agree to participate in this study after you sign this form, and the above assessments show that you are safe to continue, you will be randomized as to which device you use first in the research project: either your own prosthetic ankle, or the DSR ankle. The treatment you get first will be chosen by chance, like flipping a coin. Neither you nor the study personnel will choose what treatment you get first. You will have an equal chance of being given either treatment.

You will be using the DSR ankle only when with the Shirley Ryan AbilityLab research team and will not be taking it home for home-use at any time during this study.

Training Visits (2-4 visits): You will receive 2-4 sessions of training over 2-3 weeks (i.e. 1-2 sessions per week at 2-3 hours per session.) Training will focus on safe and effective walking over different types of surfaces, both indoor in the research space, and outdoor on sidewalks and streets in the area around Shirley Ryan AbilityLab. It will include walking over level surfaces, turns, uneven surfaces, ramps, curbs, and crossing streets. It will also include working on balance and fall prevention. Tasks can be modified or excluded based on your comfort level. The sessions will include device tuning (adjustment of the ankle study device or other components) and adaptation to your needs. During training, you will be wearing a gait belt or using overhead harnessing for safety, as needed. You will also wear a wireless foot-tracking

sensor on top of your shoe on your prosthetic side, to help us measure the way your ankle and foot move when you are walking during training.

Before and after each session, heart rate, blood pressure, and oxygen saturation will be recorded along with skin checks and asking you about pain levels. We will also ask you about how hard you feel like you are exerting yourself when you are performing the activities.

The DSR ankle will be used and fitted to your own socket. If necessary, a duplicate socket may be fabricated in order to allow for proper alignment and safe use. This duplication will be performed by a certified prosthetist on the research team. If your own socket is used, your own prosthetic components will be restored back to your socket at the end of each session.

Testing Visits (1-2 Visits): After you have completed the training and feel comfortable walking with the DSR ankle, you will have the following testing performed:

Biomechanical:

You will be asked to walk a minimum of 30 strides on a flat surface, as well as 30 strides up and down an ADA recommended ramp, to record information of your steps. You will walk at your own self selected pace. You will also stand on force plates on a flat, inclined, and declined surface, as well as take steps across the force plate.

Clinical Outcome Measures:

You will be asked to complete the following tests while you are in the lab:

- 10 Meter Walk Test
  - You will be asked to walk for 10 meters at a speed that you feel comfortable, and then at a fast speed, while we record the amount of time it takes you to walk this distance. You will be asked to do this 3 times at each speed.
- 6 Minute Walk Test
  - You will be asked to walk for six minutes at a pace which you choose and the distance you are able to go over the 6 minutes will be recorded. You can stop and rest during the test if you need to.
- Functional Gait Assessment (FGA)
  - The FGA is a 10-item test that tests your abilities such as walking backwards and with your eyes closed.
- Hill Assessment Indices
  - This test looks at how you walk when you go up and down an indoor ramp.
- Amputee Mobility Predictor Assessment Tool (AMP):
  - This tests has you perform a series of standing and walking tests to evaluate your overall mobility and balance in your prosthesis.
- Timed Up and Go

  You will be asked to stand up from a chair, walk 3 meters and sit down while the therapist times how long this takes. This may be repeated up to 3 times at the assessment visits and training visits.

Patient reported Measures:

You will be asked to complete the following questionnaires or surveys during your Testing visits:

- Orthotics Prosthetics User Survey
    - You will answer questions about your function and satisfaction with orthotic and prosthetic services.
- Numerical Pain Rating Scale
    - You will be asked about the intensity of your pain intensity from 0 (zero) to 10 (ten) scale, with 0 being “no pain” to 10 being “worst pain imaginable” while performing testing activities.
- Borg Rating Scale
    - A 6-20 item scale that measures how hard you feel like you are working during a testing activity.
- Research Subject Interview
    - You will be asked your general thoughts on your own ankle and the DSR ankle, such as what you like / don’t like about how each works for you. You will also be asked about any goals or activities you would like to see improved while using your prosthesis.

Exploratory Measures:

You will be asked to complete the following exploratory items.

- GAITRite Measurements
    - You will be asked to walk on an electronic walkway about 14 feet long that contains sensor pads imbedded in a carpet. The walkway collects information about your foot placement and speed. You will be asked to walk across this walkway at a speed that you find comfortable, as well as at a fast speed.
- Outdoor 10 Meter Walk Test on a Sidewalk
    - You will be asked to walk a distance of 10 meters on a sidewalk outside of Shirley Ryan AbilityLab, at both your self-selected speed, and your fastest but safest speed.

You will wear a wireless foot-tracking sensor on your prosthetic foot during the testing session.

You may be video recorded or have pictures taken during the training and testing sessions. These items are used for data analysis by the research team, to help troubleshoot potential issues for fit and functionality, to help aid in training other members of the research team, or for presentations. You may choose to limit if and how these items can be used in the Optional Elements section below.

For all testing, a gait belt or overhead harnessing will be used for safety, as needed.

Once all Testing Visits are complete, you will have a two week break before you return for training with the other device. This is done to avoid effects from the first training. The same protocol (training and testing described above) will be performed with your own prosthetic device and the experimental device.

Additional training or testing visits may be required to complete all research activities, in order to ensure your comfort and safety with using the device, or in the event of a technology or sensor malfunction, as your schedule allows.

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.

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

There are some risks of using the DSR ankle, similar to the risks of using other prosthetic ankles and also with the procedures and testing used in this study. These risks include:

Risks of training and activities

- You may experience an increase in respiration, shortness of breath, increased heart rate, change in blood pressure and/or dizziness. These experiences are common due to an increase in physical activity you may experience as being a part of this study, and are no greater than what is normally experienced during a typical physical therapy session or exercise. You will be permitted to stop and rest at any time during the study. The researcher will ask you to report your pain and exertion and also monitor your heart rate and the level of oxygen in your blood. They will also monitor you throughout the training and testing and during each session. The study session will stop immediately and standard medical procedures will follow any rare event of prolonged or worsening discomfort.

- There is a risk of falling during training and testing. You will be supervised for all study visits by a licensed clinician. During testing and training, your clinicians will use a gait belt or overhead harnessing for your safety as needed. You will be educated in the safe use of the device and may use a cane, crutch or other assistive device, as necessary. The risk of falling is similar to that during any clinical outpatient physical therapy session.

- There is a risk of muscle soreness due to increased physical activity during training and testing sessions. You will work with licensed physical therapists. Adequate rest will be given and you will be monitored by the therapist for verbal or visual signs of fatigue or discomfort.

Prosthetic ankle

- There is a risk of discomfort, skin pressure or irritation, skin breakdown, pain, or swelling caused by any prosthesis worn in the study. The risk will be minimized by the physical therapist or prosthetist performing a thorough skin check before and after each time you use the device. We will also provide education to you about watching for any problems with your skin. The device fit will be regularly monitored by a prosthetist.

- Risk of device malfunction, which may hurt you in ways that are unknown, but could include increasing the risk of falling.

Sensors

- There is a risk of skin reaction to the adhesives used to adhere sensors to your body during testing sessions. The adhesive is hypo-allergenic and similar to medical tape/bandages used clinically. We will explain the signs and symptoms of skin irritation and you will be instructed to remove the prosthesis if symptoms of skin irritation appear.

Questionnaires

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

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?

Taking part in this research study will not lead to any costs to you. You will not be charged for any of the training or testing visits, or the prosthetic adjustments.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, this research may help scientists and researchers in the development of new prosthetic devices and technology.

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.

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), 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

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.

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:

- You are unable to comply with frequency of study visits
- You are unable to participate safely 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.

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. You will also receive free parking vouchers if you park in the Shirley Ryan AbilityLab garage.

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 respecting 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
- Records about study devices

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) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

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.

Permission to Take Part in a Human Research Study

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].

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 Memorial HealthCare, 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,
- 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, DPT
Institution: Shirley Ryan AbilityLab
Department: Center for Bionic Medicine
Address: 355 E Erie St, 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:

Permission to Take Part in a Human Research Study

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, or to provide feedback to you during the training and testing sessions. The researcher will not share these recordings with anyone outside of the immediate study team. Your identity may be known in these recordings.
_____	_____	The research 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. My identifiable information may be permanently available in electronic format (i.e. on the internet).
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principle 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