Study Title: Safety, Reliability, and Efficacy of the Harmony SHR^{TM} Upper Extremity Robotic Rehabilitation System in the Inpatient Rehabilitation Setting for Patients with Acute Stroke

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PROTOCOL TITLE: Safety, Reliability, and Efficacy of the Harmony SHR™ Upper Extremity Robotic Rehabilitation System in the Inpatient Rehabilitation Setting for Patients with Acute Stroke

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STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	Harmony SHR™
IND / IDE / HDE #	N/A
Indicate Special Population(s)	☐ Children ☐ Children who are wards of the state ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☐ Pregnant Women ☐ Prisoners (or other detained/paroled individuals) ☐ Students/Employees
Sample Size	40
Funding Source	Harmonic Bionics
Indicate the type of consent to be obtained	☒ Written ☐ Verbal/Waiver of Documentation of Informed Consent ☐ Waiver of HIPAA Authorization ☐ Waiver/Alteration of Consent Process
Site	☐ Lead Site (For A Multiple Site Research Study) ☐ Data Coordinating Center (DCC)
Research Related Radiation Exposure	☐ Yes ☒ No
DSMB / DMC / IDMC	☐ Yes ☒ No

OBJECTIVES:
The purpose of this study is to assess the safety, reliability, and efficacy of the use of the Harmony SHR™ upper extremity robotic rehabilitation system for persons with impaired functional use of one or both upper extremities due to acute stroke.

Primary Objectives:

1. Assess the safety of the Harmony SHR™ upper extremity robotic rehabilitation system for persons with impaired functional use of one or both upper extremities for individuals' post-stroke in the acute inpatient rehabilitation setting by monitoring the incidence of device-related serious adverse events (SAE).
2. Determine the reliability of the Harmony SHR™ as an upper extremity robotic intervention for individuals with upper extremity impairment due acute stroke in the inpatient rehabilitation setting by monitoring major device malfunctions (MDM).
3. Evaluate the use of the Harmony SHR™ device during common assessment methodologies occurring during occupational therapy activities (e.g. Fugl-Meyer (FMA), Action Research Arm Test (ARAT)).

Secondary Objective:

1. To identify optimal device application in the acute stroke population.

BACKGROUND:

Stroke is the third leading cause of long-term disability worldwide[5]. The majority of patients with stroke have limited use of their affected upper limb, limiting their ability to complete activities of daily living (ADLs) independently[5]. For this reason, improving upper limb function is a major therapeutic target in stroke rehabilitation.

Many rehabilitation programs incorporate the use of robotic devices during therapy to achieve better recovery after stroke[3]. Implementation of robotic-assisted therapy allows for the application of motor relearning theories because it intensifies therapy, provides physical assistance, delivers feedback, and quantifies the individual's movement performance[3,5]. Most robotic devices combine virtual reality technology and intensity to engage the affected upper extremity in therapeutic activities. However, the design of these robotic devices can make it difficult to apply other important principles of task specific training, such as salience and task progression, to maximize functional outcomes.

Harmony SHR™ is a unique upper-extremity robotic rehabilitation device that demonstrates the ability to support movement in one or both upper extremities while maintaining scapulohumeral rhythm during shoulder movement of a patient with limited or impaired mobility. Currently, there are very few medical devices that provide high range of motion capability and support. The design of this device allows for use during task-specific practice of ADLs such as combing one's hair or cutting food. Harmony SHR™ can enable therapists to identify neuromuscular weakness and maladaptive coordination patterns and develop targeted interventions to address these aspects of upper-limb function[1].

The objective of this study is to evaluate the safety, reliability, and effectiveness of the use of Harmony SHR™ in rehabilitation of the upper extremity in the acute stroke population. By combining task-specific training and use of this device to perform ADL tasks, we hypothesize that this will result in improved outcomes of upper extremity function for patients' post-stroke who receive standard of care.

STUDY ENDPOINTS:

1. To demonstrate that the Harmony SHR™ device is safe at providing upper extremity rehabilitation for persons with impaired functional use of one or both upper extremities post-stroke in the inpatient rehabilitation setting an outcome of: Zero (0) patient/therapist incidence of device-related serious adverse events (SAEs).
2. To demonstrate the reliability and feasibility of the Harmony SHR™ device as measured by the incidence of all device malfunctions: Zero (0) incidence of major device malfunctions (MDM)

3. To assess the efficacy of upper extremity functional training with the Harmony SHR™ device related to the following mobility measures:
    a. Primary Outcome Measures: Statistical significant change in the mean increase in the Fugl-Meyer Assessment (FMA) score at post-evaluation from baseline as compared to a matched control group who receive a similar dose of standard of care.
    b. Secondary Outcome Measure: Similar statistical comparisons as the primary outcome variable will be performed using the Action Arm Reach Test (ARAT).
    c. Exploratory Outcome Measures: Similar statistical comparisons as the primary outcome variable will be performed to the following clinical outcome measures: Manual Muscle Test, Quality Indicator, Modified Ashworth Score, and Pain Scale.

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):

Description of Investigational Device

Harmony SHR™ is a wearable exoskeleton for robotic rehabilitation of the upper extremities. Harmony SHR™ supports therapy of a seated patient and is attached to the patient's upper extremities using the provided patient attachments. Throughout therapy, the device compensates for its own weight in addition to a fraction of the weight of the patient's upper extremity. Harmony SHR™ is also capable of mirroring the motion of one patient upper extremity to the other. The device can guide one or both patient upper extremities through preprogrammed exercises that are selected and customized by the therapist.

Determination of Non-Significant Risk Status of Device

Harmony is a robotic exoskeleton intended for rehabilitation of patients who have lost or have restricted function of their upper extremities due to central or peripheral nervous system damage, spinal, and muscular or bone-related disorders.

- Harmony is an exoskeleton not an implant.
- Harmony is not intended for supporting or sustaining human life and is applied on patients that are deemed to possess basic cognitive and communication ability to follow directions from a therapist or healthcare professional.
- While Harmony may support assessment of the Range of Motion of a patient's upper extremity, it is not intended to be used for diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health.
- Harmony is non-invasive and is worn as an exoskeleton by the patient under the supervision of a healthcare professional. Harmony supports the patient in range of motion assessments and in performing rehabilitative exercises at the discretion of the medical professional/therapist. It is set up with mechanical, electrical, and software risk control measures to ensure the safety of the patient and the healthcare professional administering treatment. Therefore, it does not pose serious risk to the health, safety, or welfare of a subject.

Based on the above analysis, Harmony is not a significant-risk device.

PROCEDURES INVOLVED:

1. **Screening Procedures:**
   Individuals with stroke who have been admitted as inpatients to the Shirley Ryan AbilityLab will be considered for enrollment in the study. Study personnel will assess potential eligibility of individuals based on inclusion criteria through a medical chart review in the Cerner electronic medical record. Potential subjects may also be referred to study staff by physicians and other clinicians. Study staff will then approach individuals to ask if they would like to participate in the study, confirm inclusion/exclusion

criteria, including participant sizing and set up of the device, and obtain a written informed consent as appropriate. Following screening procedures, confirmation of eligibility, and signing of the consent form, participants will be randomized into the following groups:

Optimization group: up to 10 participants will be enrolled to identify optimal device application in the acute stroke population. These participants will not be randomized into the intervention group or control group. They will receive the same treatment as the intervention group. The purpose of this group is to 1) train study staff prior to randomization and 2) ensure that the inclusion/exclusion criteria is adequate.
Intervention group: functional task training with use of the Harmony SHR
Control group: functional task training without the use of the Harmony SHR

Medical clearance will be obtained from the subject's physician prior to participation in this study.

2. **Baseline Testing:**
   - **Participants will complete:**
     - Medical intake questionnaire (age, diagnosis, past medical history, hand dominance, medications)
     - Manual muscle test (MMT)
     - Action Research Arm Test (ARAT)
     - Fugl-Meyer Assessment (FMA)
     - Modified Ashworth Scale (MAS)
     - Shoulder pain assessment using the either the visual analog scale or numeric pain rating scale.
   - **QI scores** in addition to any of the listed or other outcome measures will be mined from the patient's chart in the Cerner electronic medical record and recorded in the subject's research file. In the event, that the score is not in the patient's chart, it will be performed by study staff.
   - **Participant sizing and set up of the device:** This will involve obtaining physical measurements of the participant as needed for proper fitting of the device, including but not limited to the following:
     - Body weight, circumference of the bicep, length of the forearm from styloid to olecranon, length of the upper arm from the olecranon to the acromion, shoulder breadth from the acromion to acromion, seated shoulder height of the subject.
   - **Assessment of UE range of motion supported by the device**: This involves the participant performing a series of active and passive motions while in the device:
     - ROM supported by the device, weight support/gravity compensation, and bilateral movements.

3. **Intervention sessions:**
   - All inpatients in the study will receive standard of care occupational therapy (OT) throughout their length of study. The study intervention group or control group will both receive a matched dose of an additional one (1) hour of either the study device intervention or standard of care OT.
   - Participants will be randomized to standard of care control group or intervention group based on a random number generator.

- After completion of baseline testing, participants in the intervention group will be scheduled for up to 24 intervention (based on their inpatient length of stay) sessions using the Harmony SHR™. Each session will last up to 60 minutes. All participants will be set up by research personnel with the device but activities to be performed with the device will be customized for each participant based on level of ability. Activities will also consist of tabletop unilateral and bilateral tasks, including but not limited to:
    i. Brushing hair, lifting weighted can, opening/closing of ADL containers, cutting of simulated food, brushing teeth, and other ADLs which are task-specific in nature.
- After completion of baseline testing, participants in the control group will be scheduled up to 24 intervention sessions of 60 additional minutes of standard of care.
- All sessions will be completed by a trained researcher and/or licensed occupational therapist. Interventions will also focus on principles of high-intensity, task-specific, massed-practice, and variability.
- Participants will be continuously monitored for fit and comfort of the device, including skin inspections at the beginning and end of each session as well as intermittent checks as needed throughout the session to assess any skin breakdown or irritation that may occur as a result of using the device. All participants will be permitted to stop the activity and rest at any time during the session.

4. **Endpoint Testing:**
    - **Subjects will complete the following outcome measures:**
        - MMT
        - ARAT
        - Fugl-Meyer
        - MAS
        - Shoulder pain assessment using the either the visual analog scale or numeric pain rating scale.
    - **QI scores** in addition to any of the listed or other outcome measures will be mined from the patient's chart in the Cerner electronic medical record and recorded in the subject's research file. In the event, that the score is not in the patient's chart, it will be performed by study staff.
    - **Assessment of UE range of motion supported by the device**: This involves the participant performing a series of active and passive motions while in the device:
        - ROM supported by the device, weight support/gravity compensation, and bilateral movements.
    - **Subjects will be administered a questionnaire** comprised of qualitative questions related to their perspective on use and comfort of the device.

Vitals will be assessed as needed throughout baseline, intervention, and endpoint testing sessions. Subjects will also be given rest breaks as needed throughout each session.

OUTCOME MEASURES:

Quality Indicator (QI): The QI evaluates the level of disability, and how much assistance is needed for a subject 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.

Action Research Arm Test (ARAT): The ARAT is a 19 item observational measure used to assess upper extremity performance (coordination, dexterity, and functioning) in stroke recovery, brain injury, and multiple sclerosis. Items comprising the ARAT are categorized into 4 subscales (grasp, grip, pinch, gross motor) and arranged in order of decreasing difficulty, with the most difficult task examined first, followed by the least difficult task. Task performance is rated on a 4-point scale, ranging from 0 (no movement) to 3 (movement performed normally).

Fugl-Meyer Assessment (FMA): The FMA is a stroke-specific, performance-based impairment index designed to assess motor functioning, balance, sensation, and joint functioning in patients with post-stroke hemiplegia. For the purposes of this study, only the upper extremity motor functioning domain will be assessed. This domain is comprised of assessing movement, coordination, and reflex action of the shoulder, elbow, forearm, wrist, and hand. Scoring is based on direct observation of performance and scale items are scored on the basis of ability to complete the item using a 3-point ordinal scale where 0 = cannot perform, 1 = performs partially, and 2 = performs fully.

Manual Muscle Testing (MMT): The purpose of this test is to evaluate the strength of the upper extremities by having the participant hold the arm in a position while the researcher applies manual resistance.

Modified Ashworth Scale (MAS): The MAS is a 6-point ordinal scale used to grade the amount of hypertonicity in individuals with neurological diagnoses. A score of 0 indicates no increase in tone while a score of 4 indicates rigidity. Tone is scored by passively moving the individual's limb and assessing the amount of resistance to movement felt by the examiner.

Visual Analog Scale or Numeric Pain Rating Scale: The 0-10 rating scale for pain is used to gain a subjective report of the intensity of a person's pain. Zero represents "no pain" and ten represents "the most intense pain imaginable". A meaningful change would be plus or minus 3 points.

Patient questionnaire: This questionnaire will ask for the participant's feedback regarding their perspective on use and comfort of the Harmony SHR™ during the training sessions. It will be completed at the endpoint testing session.

Video recording and/or pictures may be taken of the participants during assessments and/or during the training sessions. These may be used to for presentations and training of other research personnel. All attempts will be made to ensure the images or videos used are devoid of any identifying information. Each participant may choose to limit if/how these items may be used, as indicated during their consent process.

DATA AND SPECIMEN BANKING

Data will be collected and kept confidential and compliant with HIPAA requirements. All personal information and study documentation that can identify participants will be kept secure to protect their privacy and will never be shared at any time with any person or entity. Data collected during the study and shared with others will reference participants only by a de-identified alphanumeric code. The "master list" linking personal information to the alphanumeric code will not be shared and will be kept separately in a secured location.

All data will be captured in electronic format and stored on the secure and password protected network and devices managed by the Shirley Ryan Ability Lab. Electronic folders will be private with limited access as determined by the PI.

De-identified data will be stored indefinitely. If participants give written consent to be contacted for future studies, this information will be kept separate from de-identified data files, in locked cabinets accessible only by authorized research personnel. All other information will be destroyed in accordance with HIPAA and IRB compliant guidelines.

SHARING RESULTS WITH PARTICIPANTS

There is no intent to share information with participants. However, if a participant requests information about their individual results, the results of their outcome measures will be shared verbally. No results of other participants will be shared to maintain patient confidentiality.

STUDY TIMELINES

Study participation from initial consenting to post-intervention testing is anticipated to last up to one month, but may vary based on participant availability and length of inpatient stay. We anticipate ongoing enrollment for 1 year.

Given the investigational nature of this device, there is no power analysis or statistical procedure to estimate the target enrollment number. The target enrollment number is determined by the maximum number of participants we could logistically test in one year. Enrollment will continue until recruitment target number has been met. Findings from this study will establish the reliability and efficacy of this device in a sample population. As a result, we will be able to comment on the minimum effect size for future studies.

DEFINITION OF SAFETY END POINT

A serious adverse event (SAE) is one that meets one or more of the following criteria:
1. Results in death
2. Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
3. Results in inpatient hospitalization or prolongation of existing hospitalization
4. Results in a persistent or significant disability or incapacity
5. An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

DEFINITION OF THE RELIABILITY END POINT

A major device malfunction (MDM) is one that meets one or more of the following criteria:
1. The device failed completely to function as intended which include components such motors, batteries putting the participant or therapist at risk for injury.

DEFINITION OF PRIMARY EFFICACY VARIABLE

A statistically significant mean change in Fugl-Meyer score (FMA) measured between post-evaluation and baseline in the intervention group compared to the standard of care group.

INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria

- Limited or impaired functional use of one or both upper extremities due to stroke

- Currently admitted to the Shirley Ryan AbilityLab as an inpatient
- Minimum passive Range of Motion requirements as follows:
    - Shoulder flexion: 90º minimum with zero starting point of arm perpendicular to the floor and 90º measuring at a right angle parallel to the floor in the sagittal plane
    - Shoulder abduction: 90º minimum with zero starting point of arm perpendicular to the floor and 90º measuring at a right angle parallel to the floor in the coronal/frontal plane
    - Shoulder rotation: tolerating of don/doff position, depending on the degree of ER required for that position
    - Elbow flexion: 90º minimum with zero starting point of arm perpendicular to the floor and 90º measuring at a right angle parallel to the floor in the sagittal plane
    - Wrist pronation: 0º minimum with the zero starting point of the forearm in neutral with the palm of the hand pointing inward and the thumb pointing up, perpendicular to the floor
- Have skeletal measurements within the ranges specified:
    - Seated shoulder height in range of 840 mm to 1122 mm measured as the sum of the following:
    - Seat of chair to acromion process of seated patient
    - Height of the chair
    - Shoulder Breadth in the range of 324mm to 443mm measured between the acromion process in one scapula to the acromion process on the other scapula
    - Humeral length in the range of 250mm to 350mm measured between the greater tubercle to lateral epicondyle
    - Ulnar length in the range of 228 mm to 306 mm measured between the olecranon to head of ulna/styloid process
- 21 years of age or older
- Ability to safely transfer from mobility device to standard chair with no armrests or with the assistance of a licensed occupational therapist/trained research staff
- Able and willing to give written consent and comply with study procedures

Exclusion Criteria

- Pregnant
- Pressure injury or exposed broken skin at sites of contact with device
- History of mastectomy and/or axillary lymph node resection or history of active lymphedema in upper extremity
- Recent sternotomy/active sternal precautions
- Recent pacemaker/ICD placement with active pacemaker precautions
- Inability to tolerate upright position and traditional therapy outside of the device
- Spasticity >3 on the Modified Ashworth Scale (MAS)
- Medical line (e.g., IV, PICC, dialysis port) at contact points
- Heterotrophic ossification
- Unresolved deep vein thrombosis
- Fixed joint contractures that limit movement required to use device
- Inability to express pain/discomfort
- Presence of a condition that in the opinion of the Investigator would compromise the safety of the patient or the quality of the data.

RECRUITMENT METHODS

Patients with upper extremity deficits due to a neurological injury will be recruited from the Shirley Ryan AbilityLab inpatient units. SRAlab-approved flyers will be hung at this facility to advertise this study. We will also email flyers to Shirley Ryan AbilityLab physician clinics for clinicians to provide to patients. Clinicians at this location will be informed of the inclusion and exclusion criteria for this study in order to refer appropriate subjects. Potential subjects will also be identified via medical chart review using the Cerner electronic medical record or by referral from the patient's primary occupational or physical therapist and/or their primary physician. Additionally, we will screen the inpatient admissions list in the Cerner electronic medical record for patients admitted with a diagnosis of a neurological injury such as a stroke, spinal cord injury, or a brain injury. Once verbal permission is obtained from the patient, the research personnel will approach the patient regarding study specifics. If the patient meets the inclusion and exclusion criteria, research personnel will ask if the patient is agreeable to participation in the study and will obtain informed consent.

In addition, we would update our website (www.sralab.org) to include this research project under current clinical trials and studies. Monitors throughout the Shirley Ryan AbilityLab will advertise for recruitment for this study.

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Subjects will attend up to 24 intervention sessions lasting up to 60 minutes each in addition to a baseline and endpoint testing session which will each last up to 4 hours. Subjects will receive $20 for each intervention session that is completed and $50 for the baseline and endpoint testing sessions.

WITHDRAWAL OF PARTICIPANTS

Participants can be removed from the study at any time at their own request or they may be withdrawn at the discretion of the investigator for safety, behavioral, or administrative reasons. Data collected until the point of withdrawal will be maintained.
The reason(s) for discontinuation will be documented and may include:

- Participant voluntarily withdraws from study
- Participant withdraws consent
- Participant is unable to comply with protocol requirements
- Research staff decides continuation on the study would not be in the best interest of the participant

RISKS TO PARTICIPANTS

Possible risks from participation in this study may include, but not limited to the following:

- **Skin Irritation/injury:** The hand and upper arm attachments may cause skin irritation and have a remote likelihood of causing skin injury. This risk will be minimized by a thorough skin check performed by trained research personnel at each session as well as asking for participant feedback. Adjustments to sizing, placement of additional padding, and amount of device assistance will be done in order to address concerns.
- **Pain/Discomfort:** Users may experience pain or discomfort while doing rehabilitation exercises using the device.
- **Worsening of Spasticity:** Participants with spasticity might experience a transient or permanent worsening of spasticity.
- **Joint Subluxation/Worsening of Subluxation/Sprain:** Due to the large range of motion of Harmony SHR, there is a rare possibility that patients may experience an onset of subluxation or worsening of existing subluxation upon use of the device. Users

with reduced range of motion in the shoulder and arm have a higher likelihood of experiencing a sprain and/or the onset/worsening of subluxation.

- **Transient Numbness or Tingling/Nerve Impingement:** Though improbable, there is a likelihood of the participant being subject to transient numbness or tingling and/or nerve impingement in the event that the device is improperly set up or used by a user with a compromised back/spine.
- **Impact Injury:** The use of an exoskeleton requires a heightened situational awareness on the part of both the User and the therapist. In the event that the user does not perceive, comprehend, or project the behavior of the exoskeleton appropriately, there is a remote likelihood of impact injury such as a contusion or concussion to the user. Personnel will be trained to ensure that use of the device is supervised to mitigate the occurrence of this risk.
- **Dislodged medical devices:** There is a remote likelihood that devices such as an ostomy pouch or feeding tube may become dislodged while using the device. Only trained research personnel will be initiating set up and use of the Harmony SHR™ to minimize these risks.
- **Muscle Soreness:** There is a risk of muscle soreness from exercises during the intervention sessions. Trained research personnel will be initiating testing and training sessions with simple activities, progressing to more dynamic, complex activities when it is clear to do so. Adequate rest periods will be provided as needed.
- **Device Malfunction:** The device itself could malfunction. All activities will be performed with close supervision from trained research personnel to monitor device function during use.
- **Infection:** The device is required to be cleaned between uses. However, the user may be exposed to the likelihood of infection if this is not followed. Personnel will be trained to ensure appropriate cleaning protocols are performed.
- **Risk of Loss of Confidentiality:** This risk will be minimized by not including personal identifying information on forms (subject will be assigned a research study number)
- **Pregnancy:** We do not know the effect of the investigational medical device on babies before they are born. Use of the investigational medical device may involve unknown and unforeseen risks to a pregnant woman, an embryo, or fetus (unborn baby). Therefore, women who are pregnant will not be recruited for this study

POTENTIAL BENEFITS TO PARTICIPANTS

There is a possibility the device may be beneficial to the participant such as improved passive and/or active range of motion, improved strength, improved motor control, and/or reduced pain. However, participation in this study may also result in no direct benefit.

DATA MANAGEMENT AND CONFIDENTIALITY

Data will be collected and kept confidential and compliant with HIPAA requirements. All personal information and study documentation that can identify participants will be kept secure to protect their privacy and will never be shared at any time with any person or entity. Data collected during the study and shared with others will reference participants only by a de-identified alphanumeric code and PHI shall be redacted. The master list linking personal information to the alphanumeric code will not be shared and will be kept separately in a secured location. Data will be captured electronically and in paper format and will be stored on a secure and password protected network and devices as well as in a locked cabinet managed by the Shirley Ryan AbilityLab. Electronic folders will be private with limited access as determined by the PI.

De-identified data will be stored indefinitely. If participants give written consent to be contacted for future studies, this information will be kept separate from de-identified data files, in locked cabinets accessible only by authorized research personnel. All other information will be destroyed in accordance with HIPPA and IRB compliant guidelines.

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS
Data will be reviewed by researchers after each intervention session. Any and all adverse events will be documented and reported in compliance with IRB regulations. If they occur in the presence of researchers, prompt medical attention will be requested via assessment by the resident on call. Health status will be assessed at all visits to ensure patient safety. Events will be recorded in case report forms. Participants will be encouraged to contact research staff or the PI to report any changes in health status. If participants experience major changes in health status, study participation will either be suspended or terminated depending on the severity.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS
Every possible precaution will be taken to protect the privacy interests of the participants. Participation in this study is completely voluntary. Trained research personnel will explain the purpose of the study and intended use of the participant's personal health information and precautions that will be taken to keep study information and data confidential. Participants have the right to withdraw at any time.

COMPENSATION FOR RESEARCH-RELATED INJURY
If the subject has any injury or illness from the study device or the procedures required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the Northwestern University principle investigator and study sponsor have decided that the injury/illness is directly related to the study device or procedures and is not the results of a pre-existing condition or the normal progression of the participant's disease, or because they have not followed the directions of the study doctor. If the participant's insurance is billed, they may be required to pay deductibles and copayments that apply. The participant should check with their insurance company about any such payments.

ECONOMIC BURDEN TO PARTICIPANTS
Costs associated with participation in the study will be offset by payment for each session ($50 each for baseline and endpoint sessions, $20 for each intervention session)

CONSENT PROCESS
Consent will take place within the Shirley Ryan AbilityLab. Authorized research personnel will review the consent document in its entirety and ensure all participants' questions are answered. Family may be present if preferred by the participant. Participants will be allowed unlimited time to review the consent, discuss with family/friends/physicians/therapy team prior to deciding to participate. Study personnel will confirm understanding of the study elements prior to signing the consent.
Individuals who are not yet adults or unable to understand English or unable to consent will not be recruited for this study.

WAIVER OR ALTERATION OF CONSENT PROCESS
Not applicable.

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)

Participant records will be kept completely confidential, and every possible precaution will be taken to protect the privacy interests of participants. Participation in this study is completely voluntary. Trained research personnel will explain the purpose of the study and the intended use of the participant's medical information and the precautions that will be taken to keep the study information and data confidential. Data will be collected and kept confidential and compliant with HIPAA standards.

Participants will be assigned an alphanumerical study ID. Identifying data will be kept in locked cabinets and password protected servers completely separate from de-identified data. Research data will be de-identified and stored in locked cabinets in the lab, accessible only by authorized research personnel. Electronic data will be de-identified and kept on secure, password protected servers at the Shirley Ryan AbilityLab. Only authorized research personnel will be able to access any of the formerly mentioned data. De-identified data will be kept indefinitely. Study documentation will be collected and stored and kept confidential and compliant with HIPAA requirements. Identifying data will be held for 7 years after the study is completed.

All personal information (names, address, email, phone numbers, etc.) gathered for this study that can identify participants will be kept secure to protect their privacy and will never be shared at any time with any person or entity. Data collected during the study and shared with others will reference participants by alphanumeric code only and all PHI shall be redacted. The master list linking personal information will not be shared and will be kept by the study PI in a secure location. All personal information linking participants to their data will be destroyed after 7 years following completion of the study.

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE

All research and procedures will be conducted at the Shirley Ryan AbilityLab, 355 E. Erie Street, Chicago, IL. Researchers will have direct access to potential participants who are admitted to inpatient units. Therefore, recruiting our desired number of participants will be feasible within the next 6 months from study start. Study data and results will be shared with Harmonic Bionics Inc, 1110 Metric Boulevard, Austin, TX. Any data shared will be de-identified to ensure patient privacy.

All research personnel will be trained on the study protocol and procedures. Experienced occupational therapists will lead the assessment and intervention sessions. The study team members are employees of the Shirley Ryan AbilityLab. They are familiar with the study site and are experienced with the study population. There will be medical resources including a resident on call and nursing staff available 24 hours/day if needed in case of an emergency.

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