Jefferson Office of Human Research
Informed Consent OHR-8
Version Date – FOR OHR USE: 12/7/21

Department: Center for Neurorestoration

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Study Title: **Motor Restoration in Chronic SCI with Combinatorial Intermittent Hypercapnic-Hypoxia and Transcutaneous Spinal Stimulation**

Lay Title: Combination Therapy with Therapeutic Air Mixture and Electrical Stimulation on the Neck

General Information Section

Informed Consent

You are being asked to take part in a research study. Research is different from standard medical care, and is done to learn something new.

Please read on to find out:

- The purpose of this research.
- How this research is different from standard medical care.
- The procedures involved.
- The risks.
- The possible benefits.
- The alternatives to taking part in this research.

You will have the opportunity to discuss this study with the research personnel. Use this information to decide if you want to take part in this research. This process is called informed consent.

Voluntary Participation

You do not have to take part in this research. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty or loss of benefits that you would normally get.

Purpose

You are being asked to participate in this research study because you have complete or partial paralysis due to a spinal cord injury (SCI). Paralysis means that you are unable to move your arms, legs, hands or feet or you have reduced use of them. The therapeutic air mixture and the study devices may help with loss of strength, function or with complications of paralysis, but there is not a guarantee that being in this study will help you.

The goal of this study is to evaluate if short bouts of breathing low oxygen with elevated carbon-dioxide separated by breathing normal air combined with non-invasive electrical spinal cord stimulation can help people with SCI to improve strength and function of muscles involved in breathing and hand function. The technical name of this breathing approach is called "acute intermittent hypercapnic-hypoxia" or AIHH.

The study will involve five (5) visits. Each session will last up to four hours. Each session will be scheduled on a separate day, with at least one week in between, hence over a minimum of four weeks. Sessions involving exposure to therapeutic air (AIHH) followed by a short 20-30 min rest break. After the rest break you will be asked to wear a noninvasive spinal electrical stimulation device and perform occupational and/or physical therapy with the spinal stimulator turned on.

Breathing the therapeutic air (AIHH) has previously been shown to improve breathing health and hand strength. This appears to happen because it causes nerve cells to build stronger connections with each other. This approach might help people who have respiratory and hand weakness. The electrical energy is delivered through surface electrodes placed on the skin, and is thought to enable the spinal cord and nerves to become active again. Studies in animals and humans suggest that improvements in hand and/or arm function and other types of functional recovery might occur with AIHH as well as electrical stimulation.

How this Research is Different from Standard Medical Care

This study will not include any standard of care procedures. This study is novel because it combines two experimental therapies i.e. AIHH and non invasive spinal electrical stimulation for improvement of function in muscles involved in breathing and hand function. This study will also explore why some individuals respond well and some do not.
As a part of this study, you will receive Physical therapy/Occupational therapy exercise based intervention which is standard of care for patients with SCI. In addition, you will receive an experimental gas mixture followed by electrical

stimulation on the neck. Both of these interventions are not part of standard of care. The novel non-invasive spinal electrical stimulation used in this study may feel similar to transcutaneous nerve stimulation (TENS) and functional electrical stimulation (FES) that are routinely performed as standard of care for SCI in Physical therapy. Unique to this study, you may undergo up to a maximum of two blood tests and one-time saliva collection

Number of Participants

In total, 29 participants will be recruited in this part of the study.

Duration

This study involves a minimum of 5 separate visits to the laboratory. The first visit will be screening, where the study physician will assess your safety and Physical/Occupational therapist will determine if you meet the inclusion criteria, followed by mapping of muscle response to magnetic and electrical stimulation of your brain and nerves. Once you qualify for the study, you will be asked to visit the laboratory on a minimum of 4 separate testing days, inter-spaced with a minimum of 1 week washout period. Testing on all 4 sessions will last for up to 4 hours. The total expected time requirement, therefore, is approximately 16 hours, following the screening visit. If a testing session is delayed due to equipment malfunction or other unexpected delays, testing may take longer. If such a delay were to occur, you may be asked to either stay longer than 4 hours (up to a maximum of 5 hours), and/or you may be asked to return for an additional session beyond the original 4 (up to 6 sessions).

Procedures and Risks

It is important that you know the procedures and risks involved in this research. These will be discussed with you and are included in detail later in this form. Review the information carefully when making your decision to take part in this research.

Possible Benefits

You may or may not personally benefit from taking part in this research. Benefits may include helping improve paralysis and some conditions related to paralysis. In addition, it may improve your function. Your state of paralysis might not get better while you are in this study. Information from this study might help researchers to better understand how to treat paralysis.

Alternatives to Taking Part in this Research

You have other options than taking part in this study. Participating in physical and/or occupational therapy with or without functional electrical stimulation is an alternative way to continue to work toward making functional progress after your spinal cord injury. The alternative to being in this study is to not take part. You may discuss alternatives to participating in this research with study staff or with your regular health care provider.

Costs

There will be no study related cost to you. If you receive a bill that you think is incorrect, please contact the research personnel. There is no plan to pay you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition. As stated in the next section on Payment, you will be paid for attending sessions. You may use that Payment to pay for travel and parking if you wish.

Payment

All participants are expected to be within the local Philadelphia area; therefore no hotel or airfare reimbursement will be permitted. The estimated travel costs are as follows:
Participants will be reimbursed up to $50 for each test visit and $25 for screening visit.
Mileage reimbursement will be at the government 2022 rate of $0.56 per mile.
Parking will be reimbursed and may require the use of a TJU voucher.
The maximum amount of parking-and-travel cost per person will be $50 per visit.
All payments from Jefferson will be in the form of a ClinCard, a kind of debit card that you can use to pay for any type of product or service just as you would use a regular debit or gift card.

Ending Study Early

There are a number of reasons you may decide or be asked to stop the study early (example: medical issues). You may also have to stop the study early even if you do not want to. You and the research personnel will discuss the reason if this becomes necessary. If you do leave the study early, you may be asked to complete some of the procedures described in this form.

New Information

New information may come out during this study. You will be given any new information that could change your decision to take part. You may ask to see the information collected about you, but not until the entire study is complete. You will be given any research results that could affect your health.

Detailed Information Section

Procedures

While you are in this study, you will undergo different procedures which are described below. Please note that additional tests and procedures may be needed to check on your health condition.

This study consists of four (4) intervention visits and one (1) baseline assessment visit, with at least 1 week interval between sessions. During sessions, you will be asked basic questions about you and your health and then undergo exposure to therapeutic air mixture (AIHH), non-invasive electrical stimulation, and functional testing. In addition, up to 10 ml blood will be drawn at the beginning of combinatorial treatment session and saliva sample will be collected once.

1. **Box & Blocks and Pinch and Grip Force Assessments**: These functional tests will measure your strength and ability to use your upper extremity and hand.
2. **Maximum inspiratory pressure**: You will be asked to exhale completely and attempt a maximal inhalation through a mouthpiece for at least 2 seconds against resistance. The mouthpiece connected to a pressure transducer will record the amount of force you can generate to inspire air.
3. **Mouth occlusion pressure:** This measure will be obtained while you breathe through a mouthpiece connected to a 2-way valve in a closed circuit. The valve through which you will be inhaling air will be momentarily occluded without your awareness, after you have expired air, until the next breath.
4. **Magnetic stimulation (cervical, CMS and transcranial, TMS) and electrical nerve conduction study**: CMS, TMS, and electrical nerve conduction studies are safe and non-invasive nerve stimulation techniques that have been used in clinical and research settings for over 30 years. We will perform a series of magnetic stimulations on top of your head (known as transcranial magnetic stimulation) and over the back of your neck (known as cervical magnetic stimulation) or in your forearm and hand in order to activate the phrenic nerve that innervates the diaphragm and/or hand muscles. These procedures are commonly used in research and are well-established. During these stimulations, we will record electrical activity of the diaphragm muscle using surface electrodes placed on the chest wall over your ribs. We will then record your resting breathing and monitor cardiovascular variables like heart rate and blood pressure. You will then breathe a predetermined gas concentration for approximately 30 minutes while we record breathing and cardiovascular responses. We will continue to

monitor these readings for up to 1 hour after exposure. We will then perform a final set of magnetic stimulations to compare with baseline.

5. **Surface electromyography (EMG):** EMG will be conducted to record the activation of breathing muscles during the respiratory tests. By analyzing the electrical activity generated during a muscle contraction, EMG analyses allow us to understand timing and amplitude of muscle activation as well as the frequency content of the EMG signal. Using a standard surface preparation (cleaning the skin with water or alcohol pad, shaving of excess hair) and electrode placement, EMGs will be collected from your muscles involved in inspiring air using surface EMG electrodes. EMG sensors will be attached to the skin with hypoallergenic medical tape. Before data is collected we will check to ensure that the quality of EMG signal is free from noise and interference. The electrode gel used during electrode placement is slightly abrasive and may cause skin irritation. We encourage you to inform the researcher of any skin conditions and discomfort during electrode placement.
6. **RT Xcite device:** This device uses electrical stimulation, which is a form of electrical energy that passes through your skin and the tissue below your skin, such as your fat and muscles, down to the nerves and nerve cells that make up your spinal cord. The type of electrical energy being used is thought to enable the spinal cord and nerves to become active again after an injury or illness which has caused paralysis. Studies in animals and humans suggest that improvements in hand and/or arm function and other types of functional recovery might occur with this type of stimulation. The device uses gel electrodes that are placed on your skin. These electrodes will be placed on specific locations on the skin of your neck and/or back and will be connected to a stimulator. The electrodes have a hydrogel sticky surface; so if you have an allergy to any type of gel or adhesive material, please inform the study staff.
7. **Respiratory resistance training**: This intervention will involve using a special mouthpiece to provide resistance when you are inspiring (breathing in) or expiring (breathing out) air from the room around you. You will be asked to breathe against resistance that will be based on your own individual respiratory strength (determined prior to starting the intervention). You will be asked to complete three training sets of approximately 6-12 repetitions of *breathing in* and three training sets of approximately 6-12 repetitions of *breathing out*. You will be given short rest periods of about 10-15 seconds of normal breathing between repetitions. We will monitor your heart rate and blood pressure at regular intervals. You may take longer rest periods if needed.
8. **Functional strength training:** you may be asked to perform motions Of different parts of your body, to the best of your ability. This practice will be familiar to you, as it will be exactly what is done in traditional,

standard-of-care occupational and physical therapy; and it will be performed with a certified occupational or physical therapist. You will be given rest periods following the same guidelines that therapists typically use in outpatient rehabilitation. We will monitor your heart rate and blood pressure at regular intervals. You may take longer rest periods if necessary.

9. **Blood Draws**: Following completion of the initial paperwork, you will be asked for a blood draw. A registered nurse/phlebotomist will collect 10 ml of blood which is roughly equal to 2 teaspoons. The blood sample will be collected from your arm by inserting a small needle. Your blood will be drawn only once, which is during the first intervention session. It will be stored in a secured location with your coded study ID until the end of the study. After the study is over the sample will be destroyed and discarded.

10. **Saliva Collection**: At one time point during your five research visits, you will be asked to submit 2ml of saliva by spitting into a sterile container. The collected saliva will be processed and analyzed to determine if you respond *or not* to treatment based on your individual genetic differences. The saliva will be collected only once and stored in a secured location with your coded study ID until the end of the study. After the study is over the sample will be destroyed and discarded.

11. **Blinding:** Participants and blinded assessors will be made aware of possible air mixtures, but not made aware of the intervention delivered. Based upon reports from participants (N=6) blinded during prior study (Hayes et al., 2014), 4 of 6 guessed incorrectly or were uncertain of the Acute Intermittent Hypoxia (AIH) intervention received, suggesting our prior blinding and air delivery methods were effective; similar uncertainty was reported in all published trials in humans with SCI. However, participants receiving AIHH intervention with elevated CO_2 pressure are likely to experience mild levels of dyspnea/ air hunger and are therefore more likely to correctly guess the intervention. Regardless, we will rigorously monitor and quantify blinding integrity by asking blinded participants and assessors to guess the intervention received at the end of each intervention and to indicate guess confidence using a Likert scale (Likert, 1932; Brunoni et al., 2014). We will use a contingency table and Fischer's Exact Test to determine if the probability of correct guessing is different from chance.

Risks

Taking part in this study involves certain risks. There may also be risks that are not known at this time. If you have any medical issues during this study, call the appropriate number in the contacts section of this form.

AIHH and Respiratory and Hand Muscle Strength training: The risks associated with AIHH and respiratory strength training are minimal and the lower oxygen levels associated with AIHH have been shown to be easily tolerated without discomfort or negative responses. Specifically, many studies have shown that AIHH at the levels and dosage used in this study, and respiratory or hand muscle strength training can be delivered safely, with no adverse events.

Furthermore, we will work to ensure your safety and comfort throughout all of the study procedures. We will ask you questions regularly to monitor your general health, such as questions about your pain, spasticity, medication-use, or sleep. You will be asked to let us know if you have any dizziness, headache, vision changes, or any other feeling of discomfort throughout the study. We encourage you to let the study staff know about your comfort and how you are feeling throughout all study procedures to ensure your safety and comfort. A licensed clinician with experience working with individuals with spinal cord injuries will oversee all participant testing and interventions. You will complete the study procedures while seated or lying down in a safe and supported manner and your responses to testing and interventions will be observed closely. Additionally, you will be allowed to take rest breaks as often as needed.

Common discomforts that may occur in this study and steps to alleviate them are:

1) The mask used to deliver the low and higher level oxygen mixtures may be uncomfortable. The fit and placement of the mask will be adjusted as necessary to ensure maximum comfort. Additionally, the mask will be removed during periods of breathing normal room air to give you a break from wearing the mask.

2) You may feel sleepy during delivery of either gas mixture. This may be due to breathing low-oxygen air, or due to sitting still in a reclined position. Feelings of sleepiness typically last only for the duration of the intervention. Both gas mixtures will be delivered while you are seated in a semi-reclined position with head, arm, and feet support as necessary for comfort, and to ensure safety. Additionally, study staff will talk with you throughout the interventions to keep you engaged and encourage you to stay awake.

3) You may feel slight discomfort and/or fatigue during or shortly after bouts of respiratory strength training due to the effort involved in completing the training. You will be provided as much rest as necessary in between sets of training exercises to lessen any fatigue. Heart rate, blood oxygen saturation, and blood pressure will be continuously monitored throughout respiratory strength training to ensure that you are not over-exerting yourself during the training.

Rare but possible risks in this study and steps to alleviate them are:
1) Breathing low levels of oxygen and slightly elevated carbon-dioxide (during AIHH) causes low levels of oxygen and high levels of carbon-dioxide in the blood. Side effects of low blood oxygen levels can include lightheaded sensations, dizziness, reduced vision, or euphoria. If you report any of these, or other general discomfort during the low-oxygen intervals, delivery of AIHH will be terminated. The effects of breathing intermittent low levels of oxygen are well-studied in humans and methods proposed here are deemed safe. Our mild AIHH dose is based on human studies that delivered AIHH without unwanted side effects.
2) Significant sudden increases or decreases in heart rate, respiratory rate, or blood pressure may be signs of an adverse response to study procedures. To minimize risks from sudden increases or decreases in heart rate, respiratory rate, or blood pressure, these vital signs will be monitored throughout all study procedures. In the event that one or more of them shows a sudden change, study procedures will be stopped. Your vitals will be monitored by study staff. If you report additional discomfort or the vitals do not return to baseline in a time deemed safe by study staff, the study physician and principal investigator will be notified and/or, if necessary, emergency medical services will be contacted.
3) Reproductive risks--Because the treatment in this study might affect an unborn baby, you should not become pregnant while in this study. Since this treatment will not be given to any patients who are pregnant, all women of childbearing potential must take a pregnancy test prior to receiving any treatment on this study. We encourage all women enrolled on this study to use one of the effective birth control methods while enrolled in this study. These methods include total abstinence (no sexual intercourse), oral contraceptives ("the pill"), an intrauterine device (IUD), an etonogestrel implant (Implanon), or medroxyprogesterone acetate injections (Depo-Provera shots). If one of these cannot be used, using contraceptive foam and a condom are recommended. You must notify the study staff if you become pregnant during the course of the study.
4) During muscle activity recording (surface electromyography) adhesive from the disposable stickers might be uncomfortable when peeled off hairy skin. Hair may be shaved from the skin prior to placement of electrodes to avoid discomfort when removing.

<u>Risks associated with noninvasive spinal cord stimulation</u>: Skin surface electrical stimulation via hydrogel electrodes is known to commonly cause minor discomfort during or after stimulation. Skin irritation or redness from the electrodes. Muscle or joint stiffness, discomfort, strain and spasms. Some uncommon side effects include dizziness, allergic reaction to electrodes, bruising from being positioned, lower or elevated blood pressure, increased heart rate, shortness of breath, pain or discomfort. Rarely, burns to the skin from electrodes, bone fractures during exercise training have also been reported.

Risk associated with magnetic stimulation: Single-pulse transcranial magnetic stimulation is generally considered safe. However, there is a very low risk of seizure. Therefore, you should not participate if you have any history of seizures or epilepsy. Due to the magnetic field, your arms and shoulders may move during the stimulation and may experience shoulder and/or neck ache. There is a loud sound from the stimulation machine that may be startling but is not dangerous.

Magnetic stimulation (cervical and transcranial) is a safe and non-invasive nerve stimulation technique that has been used in clinical and research settings for over 30 years. The risks associated with magnetic stimulation are minimal; however, you may feel discomfort during the stimulations, including shoulder or neck ache for cervical stimulations. If you are uncomfortable with the higher intensities of stimulation, please let your study team know and extended breaks will be given, or if desired, no further stimulations will be performed. Using single-pulse TMS, even the highest stimulation setting is not harmful. There is a clicking sound that may be startling but is not dangerous. Although rare, seizures are a potential side effect of single-pulse TMS. In the event of a seizure or other medical emergency, emergency services (911) will be called.

Additionally, researchers will take appropriate steps to protect any information they collect about you. All data collected will be stored in secured locations such as a locked filing cabinets, on secured, password-protected computer servers, or on encrypted electronic storage devices. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your ability to be insured or employed. Questions 8 and 9 in this form discuss what information about you will be collected, used, protected, and shared.

This Research Study may also include risks that are unknown at this time. Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The Thomas Jefferson University is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that

information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies, and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

<u>Risks of Blood Draw</u>

For most people, having blood taken is quick, easy and relatively painless. Other people may feel anxious and occasionally the participant may feel unwell or faint. Therefore, you will be asked to stay under study staff supervision until you fully recover after a blood draw. Some people have a

tendency to bruise at the site of venipuncture. In order to prevent, a cotton-wool dressing will be taped over the puncture site and you will also be asked to avoid carrying anything heavy or undertake strenuous exercise within 24 hours of the blood sample collection.

Strength testing risks

Your hand and breathing muscles can develop temporary soreness following muscle strength testing. Any muscle soreness related to muscle testing should subside within 24 to 48 hours. If muscle pain persist longer than 48 hours please inform the study personal who will refer you the study physician.

Other possible risks to you may include: The electrode gel used during electrode placement is slightly abrasive and may cause skin irritation. We encourage participants to inform the researcher of any skin conditions and discomfort during electrode placement.

Costs

You may have costs for participating in this study.

There will be no study related items or services billed to you or your insurance company. There is no plan to pay you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s). If you receive a bill that you think is incorrect, please contact the research personnel. You will be responsible to pay for your travel to and from the study site and other out-of-pocket expenses such as parking.

Research-Related Injury

There is a possibility that you could have research-related injury, which is an illness or an injury that is directly caused by the study procedure. If you have a research-related injury, we will offer you reasonable and necessary care to treat injuries directly resulting from taking part in this research. Neither Jefferson nor the study will pay for costs associated with treatment of research-related injury or illness. These costs may be billed to your insurance. In addition, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan.

There are no plans for Jefferson to pay you or give you other compensation for the injury. However, you are not prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of

those involved in the research. If you think you have been injured as a result of taking part in this research study, tell the research personnel as soon as possible. Please see the contact information in this consent form.

Disclosure of Financial Interest

There are no conflicts of interest to report in this study.

Privacy and Confidentiality: HIPAA Authorization

Information will be collected about you for this study. The information will be seen by the people involved with this research. Steps will be taken to protect your identity. But the information collected about you can never be 100% secure.

HIPAA (Health Insurance Portability and Accountability Act) – This is the law that protects your personal health information.

To do this study, we need to collect, use, and share your personal health information. This form will explain why your information is being collected, what information will be collected, and who will have access to it. By signing, you are giving us permission to use your information as described in this form.

We are committed to respecting your privacy and to keeping your personal health information confidential. Your personal health information includes the information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, social security number, and medical information. The personal health information that may be collected, used, and shared for this research includes:

- Information from your medical records
- Demographic information such as name, gender, birth date, ethnicity, medical history, and health care providers
- Physical examinations, procedures, tests, labs, your medical conditions, and medications you use
- Information collected about any research related injury
- Information about mental health, sexually transmitted diseases, HIV, AIDS, drug and alcohol use, genetic test results, and other sensitive information
- Biomarker Sampling (blood, saliva)

Your personal information will be used by and shared with the following:

- Personnel at Thomas Jefferson University and its affiliates for the

purpose of this research
- Research personnel at Rothman
- Institutional Review Boards (ethics committees that review research) including the Thomas Jefferson University IRB
- Health insurance providers
- Research monitors hired by the sponsor to oversee the study and review health care records to ensure study-related information is correct
- Government Agencies like the Food and Drug Administration (FDA)
- An organization such as a contract research organization (CRO) that has been hired to coordinate the study
- Public health authorities who monitor such things as sexually transmitted diseases, HIV, AIDS, child abuse, as required by law
- Groups monitoring the safety of the study such as a data and safety monitoring committee
- Others as required by law

When your personal information is provided to some of the people listed, it may no longer be protected under the HIPAA privacy law. You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study, and the results of any study test or procedure may be included in your health records which may be seen by your insurance company and your health care providers.

This authorization does not have an expiration date. Please inform the investigator in writing if you want to end your permission to collect information/samples. Please note that anything already collected will still be used and you may not be able to continue in this study.

The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be personally identified.

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

Your private information and specimens, with the identifiers removed, could be used for future research studies or distributed to other researchers for future research studies without your additional permission.

Contacts

If you are having a medical emergency, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are taking part in this study.

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For Questions About:	**Person or Office**	**Contact Information**
The Study or Research Related Injury	Investigator: Jayakrishnan Nair, PT, PhD	352-871-5888
	Mijail Serruya, MD, PhD	215-964-7276
	Dana R. Johnson, PT, DPT	215-868-1988
If you need to contact someone other than the study personnel about a concern or your rights as a research subject	Jefferson Center City Institutional Review Board (Ethics Committee)	215-503-0203 215-503-8966 215-955-4239

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Signatures

Patient/Subject: By signing this form, you are agreeing that:

- You were given the opportunity to read this form.
- All of the information in this form was discussed with you by an investigator or other research personnel to your satisfaction.
- All your questions have been answered to your satisfaction.
- You were not pressured and you voluntarily agree to take part in this research.

_____	_____	_____
Your Name	Your **Signature**	Date

_____	_____	_____
Name of Person Obtaining/Assisting with Consent	**Signature** of Person Obtaining/Assisting with Consent	Date

By signing below, you the **investigator**, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

_____	_____	_____
Name of Investigator	**Signature** of Investigator	Date

_____	_____	_____
Name of Witness	**Signature** of Witness	Date

(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

☐ **Copy of Signed and Dated Consent Form Given to the Subject/Parent/LAR**

Optional Teach-Back Questions – These questions can be asked to help ensure that the patient understands the study.

☐ Check this box if these questions were reviewed with the patient.

We have gone over a lot of information. I would like to ask you a few questions to make sure I have done a good job explaining the study to you.

1. In your own words, please answer these questions about this study:
    a. Why are we doing this study (what are we trying to learn)?
    b. What things (including tests and procedures) will you have to do in this study?
    c. What are some of the risks of being in this study?
    d. What is the benefit of being in this study?
    e. How will being in this study be different than usual medical care?
    f. How long will you be in this study?
2. Taking part in this study is voluntary. What does that mean to you?
    a. If you don't want to be in this study, what are your other choices?
    b. What will happen if you chose not to be in this study?
3. What will we do to make sure your information remains confidential?
4. What other questions do you have about this study?