UF | Institutional Review Board
UNIVERSITY of FLORIDA

NCT04179799

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study (this "Research Study")?

Diaphragm stimulation after human spinal cord injury: Effects on respiratory neural drive and function

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator: Emily Fox PT, DPT, PhD

(352) 273 6117 (office)
(904) 742 2500 (cell)

Other research staff: Alicia K. Vose, PhD CCC-SLP

(904) 345 4998 (clinic/office)
(860) 912 8156 (cell)

4. Who is paying for this Research Study?

The sponsor of this study is the National Institute of Health -- Stimulating Peripheral Activity to Relieve Conditions (SPARC) Research Program

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

Many people who have a spinal cord injury have difficulty with breathing. The use of diaphragm pacing is one way that doctors and clinicians help people improve their ability to breath. Diaphragm pacing uses electrical signals to contract the diaphragm muscle. The diaphragm is a muscle that is under your rib cage and helps you breathe.

You are being asked to be in this research study because your breathing has been affected by a spinal cord injury and you have a diaphragm pacer or are scheduled to receive a diaphragm pacer to help you breathe. We are conducting this study to better understand how the use of diaphragm pacing affects breathing function. The goal of this research project is to study the effects of diaphragm pacing on how your diaphragm muscle functions (i.e. does it get stronger or contract better?) and your overall breathing function.

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.

b) What is involved with your participation, and what are the procedures to be followed in the research?

In general, study procedures will include (1) baseline breathing assessments, once per day, up to 3 times prior to your diaphragm pacer placement; then after diaphragm pacer placement, (2) pre- and post-assessments of breathing and diaphragm activity will be recorded to measure any changes in your breathing function following periods of your diaphragm pacer turned *on*. Additionally, you will be asked to perform an assessment that tests your overall strength and sensation. The strength test will measure the strength in your arm and leg muscles. The sensation testing will determine how your injury affects your sensation at specific places on your skin. Details regarding all study procedures are listed in Question 7.

c) What are the likely risks or discomforts to you?

Discomforts and risks of the breathing tests and tests of your spinal cord injury are minimal. Many studies have shown that these assessments can be administered safely, with minimal unwanted side effects. Sometimes the testing may cause you to feel tired, fatigued, or short of breath. Some of the test may be uncomfortable because they are difficult to perform due to your injury. We will work to ensure your safety and comfort throughout all of the study procedures. Details regarding the risks and discomforts are explained in Question 12.

d) What are the likely benefits to you or to others from the research?

No direct benefit is likely from participating in this study. The outcomes from this study may benefit future individuals with spinal cord injuries or other clinical populations with respiratory impairments.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

Your participation in this study is completely voluntary and you may stop participating at any time. As an alternative to participating in this study, you may not enroll or choose to withdraw from the study at any time. If you do not want to take part in this study, tell the Principal Investigator or other study staff, and do not sign this Informed Consent Form.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Normal clinical care is medical or other treatment or services that you would receive even if you did not participate in this research study.

As part of your normal clinical care, you would undergo assessment of your muscle strength and sensation. This is a standard clinical assessment of spinal cord injury. Clinical tests of respiratory function are also part of normal clinical care. However, these assessments will be done more often than is typically done in clinical care.

7. What will be done only because you are in this research study?

Overview of the research study:

This study involves up to 8 assessments before and after diaphragm pacer placement. Therefore the respiratory assessments (which can be part of normal clinical care) will be done more often than is typically done in clinical care. Some of these assessments will be done before and after periods of your diaphragm pacer turned on. The testing schedule and procedures are described in detail below.

Before diaphragm pacer placement: Once you are scheduled for your diaphragm pacer placement, we will measure your baseline breathing function up to 3 times (once per day) on the days leading up to your surgery. To measure your breathing, you will be asked to breathe into or from a tube or device that will measure your breathing function. You will be asked to breath in a relaxed manner and to breathe in or blow out as much air as possible. You will be asked to repeat these procedures. There will be breaks in between each test and you may rest as often as needed. Overall, the breathing assessments take approximately ~1 hour and will allow for rest breaks or interruptions as needed.

If you are enrolled after your diaphragm pacer is already placed, you will not receive baseline breathing assessments described above.

After diaphragm pacer placement: Between 1-5 days after your diaphragm pacer is placed, we will test your breathing again prior to turning on your diaphragm pacer. During this time you will also be asked to participate in a test to measure the activity of the diaphragm muscle. This muscle helps control your breathing. To measure the activity of this muscle, we will record electrical signals from the wires in your diaphragm muscle (EMGs). In order to do this, we will briefly disconnect the pacer control box. The pacer control box attaches to pacing wires that are used to stimulate your diaphragm muscle during breathing. The wires will be connected to a system that will *record* the signals from the diaphragm muscle. This test of your diaphragm muscle will take ~1 hour. These signals will be recorded while you do the clinical tests of breathing function.

After brief periods of diaphragm stimulation: You may complete up to 3 more breathing assessments and diaphragm recordings following periods of diaphragm stimulation (pacer turned on). These will be done following each of 2 blocks of diaphragm stimulation that lasts ~1-2 hours and then 1 block of diaphragm stimulation that lasts ~12-24 hours. All assessments will be completed with your diaphragm pacer turned off and disconnected.

Turning off the pacer is a common process because it is routinely done to clean the wires and change the batteries in the pacer. When the pacer is turned off you will be closely monitored. If you have difficulty breathing or if you are uncomfortable, we will help you to breathe or help you feel more comfortable. We may provide you with air that has extra oxygen in it and/or we may use a breathing bag to help push air into your lungs. If you have been using a ventilator, your medical team may reconnect you to this device or adjust the settings on the ventilator to help you breathe while the pacer is turned off. Since you are in the hospital setting for all assessments, your medical team will monitor the assessments and provide oversight for safety and to ensure your comfort. Your physician will provide oversight of the testing.

Lastly, we will conduct a clinical assessment to understand different aspects of your spinal cord injury. This clinical assessment will be performed while seated or lying down in a safe and supported manner. We will assess any muscle spasms you have in your legs, how well you are able to feel touch on various parts of your body and how well you are able to move your arms and/or legs.

You may choose not to perform any aspect of the clinical and/or breathing assessments for any reason and you may take a rest break at any time. A licensed clinician with experience working with individuals with spinal cord injuries will conduct and oversee all assessments. Your responses to assessments will be observed closely, and you will be allowed to take rest breaks as often as needed.

If you are unable to talk with us or use your voice, we will work with you to make sure we have an effective communication system to know when you feel uncomfortable or if you have questions. Your vital signs such as heart rhythm, blood pressure, breathing function will be closely monitored at all times during the assessments. We will use this information as well as your response to the testing to determine if a test should be discontinued. We will ask you to let us know if you are uncomfortable or nervous about any part of the assessment. At any time, we can delay or stop an assessment. You may discontinue your participation in an assessment or the study at any time. If an assessment is not successfully completed, you may be asked to repeat or re-attempt the assessment. All assessments will be scheduled at a time that is convenient for you and the individuals providing your care.

During the assessments, you may be asked to be photographed or video recorded during the assessment. These recordings allow us to communicate about study procedures and how individuals with spinal cord injuries complete the assessments. You will be informed if we were considering taking a photo or video during any assessment. At the conclusion of this document is a consent for the collection and use of photography and/or video recording.

At any time you may indicate that you do not want to complete any part of an assessment, including participation in a photo or video recording. You may choose not to complete this study. Participation in all portions of this study is voluntary.

Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems. These tests and test results will not be included in your medical records. This/these test(s) may need to be repeated if required for your medical care in the future. If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

Once this research study is completed, any information that could identify you might be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

8. What identifiable health information will be collected about you and how will it be used?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected and used with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits. More specifically, the following information may be collected and used with others:

- Your name, age, phone number, email address, or mailing address.
- Past medical history to determine eligibility for study participation.
- Questionnaires about your physical function health, perception of difficulty breathing, and medical status.
- Laboratory, x-ray, MRI, and other test results from past medical records as deemed necessary.
- If you provide consent for audio, video, or photography, then this information will be collected and used in a manner with which you have agreed.
- Data generated from the study activities such as data pertaining to breathing ability.
- Your social security number (SSN) will be collected for research participation purposes.

All data collected will be stored in secured locations (e.g. locked filing cabinets), on secured, password-protected computer servers, or on encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the

limited data set are required in order to protect your identity and confidentiality and privacy.

The Research Team may collect this information from other healthcare providers, who are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in Question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study Principal Investigator (listed in Question 3 of this form), study investigators at the University of Florida and research staff at Brooks Rehabilitation associated with this project.
- Other professionals at the University of Florida that provide study-related treatment or procedures.
- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).
- The study sponsor (listed in Question 4 of this form)
- United States governmental agencies who are responsible for overseeing research, such as the Department of Health and Human Services, and the Office of Human Research Protections.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this research study?

You will be enrolled in this study for up to 2 weeks.

This Authorization to use and share your health information expires at the end of the study unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this research study?

We will recruit up to 10 people to enroll in this research study. To complete this research study, we aim to have 5 adults with spinal cord injuries take part and complete the research protocol.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this research study?

The assessments that will be performed during this study pose a low risk of harm. It is possible that you will experience discomfort during the assessments. All assessments will be conducted by a licensed clinician with experience working with individuals who have sustained a spinal cord injury. All of the assessments will be closely monitored by your medical team with oversight by your physician. Your participation in the assessments is voluntary and you may choose not to participate in any aspect of an assessment.

During the tests of your breathing function, you may feel short of breath or anxious about your ability to breathe. Your breathing function and vital signs will be closely monitored during all tests. We will help you breathe or provide extra oxygen if needed. We can stop the tests at any time and you can take a break from the testing at any time needed.

To test the function of your diaphragm muscle, the diaphragm pacer will be turned off. It is normal to shut off the diaphragm pacer and this is routinely done to change the batteries or clean the connectors. As during all assessments, when the diaphragm pacer is shut off we will monitor you at all times and provide any breathing support that is needed. If you are unable to verbally communicate with us, we will have a communication system so that you are able to clearly communicate with us if you are uncomfortable or having any difficulties.

During the clinical tests of your muscle strength and sensation, you may feel nervous or anxious about the tests. You may feel frustrated that you do not move or feel things like you did before your spinal cord injury. This clinical tests will be performed in a private location, but involve asking you about sensation and movement in private areas of your body such as your rectum. This is part of normal clinical care and routine assessment after spinal cord injury, but you may feel uncomfortable during this test.

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.

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 listed in Question 3 of this form 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 University of Florida 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.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

There is no direct benefit to you for participating in this research study.

13b. How could others possibly benefit from this Research Study?

There is no direct benefit to others from the conduct or participation in this research study. Outcomes from this study may benefit individuals with spinal cord injuries who require the use of a diaphragm pacer.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

14. What other choices do you have if you do not want to be in this study?

Your other choice is to decline participation in this study. If you do not want to take part in this study, tell the Principal Investigator or the research personnel and do not sign this Informed Consent Form

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study. For example, we may analyze and present the data that we collect. If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in Question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in Question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in Question 3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from the study without your consent for the following reasons:

- If your physician indicates it is not safe or recommended that you participate
- If your medical or health condition changes such that it is not healthy for you to participate
- If your medical or health condition changes such that your status does not match the goals of the study
- If your medical or health condition or information changes and your condition does not meet our study enrollment criteria
- If the Principal Investigator, Dr. Fox, and members of the study team determine that is necessary to withdraw you from the study for administrative reasons.
- Other reasons affecting the administration of the research project
- Funding for the study stops.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this research study, will it cost you anything?

The Sponsor will pay for the medical services required as part of your participation in this study as described above in the question, "What Will Be Done Only Because You Are In This Research Study". This may include some medical services that you would have received if you were not in this study. All other medical services will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, co-payments, for those services, and for any non-covered or out-of-network services. Some insurance companies may not cover costs associated with research studies. Please contact your insurance company for additional information.

17. Will you be paid for taking part in this study?

We will compensate you for your time and involvement in this study by providing you with a gift card valued at $50.00. An additional $50.00 (loaded onto the initial gift card) will be provided after completing each assessment. Because up to 8 assessments may be completed, you may be compensated up to a total of $400.00.

To receive compensation for your involvement in this study, personal information such as your date of birth and social security number are required.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to ***nonresident aliens*** must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study staff or the investigator listed on Question 3 of this form.

18. What if you are injured because of the study?

Since this is a data collection/registry/observational study, there is a very low risk of study-related injury, However, if you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider. You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information. The Principal Investigator will determine whether your injury is related to your participation in this study. No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence. Please contact **Emily Fox PT, DPT, PhD (904) 742 2500** if you experience an injury or have questions about any discomforts that you experience while participating in this study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing Date

As a witness, you were present for the discussion of the study and observed that this study participant has agreed to voluntarily participate in this study. As a witness to this informed consent for study participation, you are not a family member of the participant or a member of the medical team caring for the participant, or a member of the research study team.

Signature of Witness Date

Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Dr. Emily Fox or her successor will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under *[his/her]* direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. Fox has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

_____ _____

Signature Date

_____ _____

Signature of Witness Date