Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: October 2014

Protocol Title: Ventilatory Support to Improve Exercise Training in High Level Spinal Cord Injury

Principal Investigator: J. Andrew Taylor, Ph.D.

Site Principal Investigator:

Description of Subject Population: Adults with spinal cord injury (Cross-sectional testing-only group).

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Why is this research study being done?

The purpose of the study is to find out if using a breathing machine during FES-row training will increase your fitness level. You are being asked to take part in this research because you had a spinal cord injury and you have been participating in FES-row training for six months or more. About 15 people that are 18 years of age or older will take part in this research study over a 3-year period.

How long will I take part in this research study?

It will take you approximately 2 to 3 weeks to complete this study. You will be required to make 3 testing visits at Spaulding Hospital Cambridge. Your total time commitment will be approximately 3 hours.

What will happen in this research study?

To be in this study you must be ≥18 years of age with spinal cord injury (American Spinal Injury Association A, B or C) at the neurological level of C5-T12.You must have been participating in FES-row training for the last 6-months or longer.

You cannot take part in the study if you have:

- blood pressure >140/90 mmHg or you are on blood pressure medication
- significant irregular heart beat
- heart disease
- chronic lung disease (COPD, bronchitis)
- diabetes
- implanted electronic cardiac device (pace maker, defibrillator)
- kidney disease
- current pressure sore (grade 2 or higher at relevant contact site)
- cancer
- other neurological disease
- regular use of tobacco
- shoulder injury that limits ability to row
- current deep venous thrombosis

Note: You may have to be removed from the study if there are any changes to the medications you take that have effects on how your body responds to exercise.

You will perform two FES-VO2max tests on separate days. During one test you will receive positive pressure through a face mask and during the other FES-VO2max test you will not. The order of the tests will be "randomized"; this means that which test you perform first will be based on chance alone (like the flip of a coin).

Consent Form Title: FESRT_NIV_consent_Xsect_V4_clean(10_017_17)
IRB Protocol No: 2016P000658 **Sponsor Protocol No: FESRT_NIV_det_pro_V4(09_20_17)**
Consent Form Valid Date: 3/18/2019 **IRB Amendment No: N/A** **Sponsor Amendment No: N/A**
Consent Form Expiration Date: 3/22/2020 **IRB Amendment Approval Date: N/A**

Specific Study Details

Screening Visit, Spaulding Cambridge: (about: 1 hour)

Instructions: You will arrive at the Laboratory between 8:00 and 3:00PM. This visit can be scheduled on a day that you would normally be rowing anyway and will add approximately 60 minutes to your normal 1-hour FES-row session.

Medical History Questionnaire. We will ask you questions about your medical history.

Height and Weight. We will measure your height with a tape measure while you are lying on an exam table. We will weigh you on a scale while you are seated in your wheelchair.

Blood Pressure and Heart Rate. Blood pressure will be measured by inflating a cuff placed around your upper arm. Heart rate will be measured by placing small sticky pads (electrodes) on your chest. Each sticky pad has a wire attached that goes to the ECG machine.

Breathing Machine Familiarization. Using the breathing machine includes wearing a full face mask that is connected to the breathing machine during your FES-row testing and training sessions. We will have you put on the mask so you have an idea what it will feel like during training.

Pulmonary Function (Breathing) Test, Spaulding Cambridge:
This is a standard test that measures how much air you can exhale. While breathing into a mouthpiece you will be asked to inhale as deeply as possible and then exhale forcefully several times. We will also ask you to breath in and out as hard as you can to measure the pressure you generate.

Specific Testing Procedures:

FES-VO2max Row Tests, Spaulding Cambridge: (about: 1 hour per test)
You will perform 2 separate FES-VO2max Row Tests on separate days in this study. In one test you will not be using the breathing machine. In one test you will not be using the breathing machine; in the other test you will be using the breathing machine.

As you have already been FES-row training for 6 months it is likely you have already performed a FES-row VO2max test. The FES-VO2max test involves rowing on a rowing machine while using the FES-device. The FES-device will be connected to you with sticky pads. You will manually control the FES-device with a button that you will push with your thumb if you are able. If you cannot push the button yourself a staff member will assist you. Pushing the button will cause your legs to move timed with the upper-body rowing movements.

The purpose of this test is to see how your heart and lungs respond to exercise. We hope to find out how much work you can do. Depending on which test you are performing you will be breathing in room air with or without positive pressure through a face-mask and the air you breathe out will be analyzed. You will also be wearing a strap that goes around your chest to monitor your heart rate and a small sensor on your forehead that measures blood flow in your brain using invisible light waves. You will need to wear shorts or loose sweat pants for this test**.**

Once you are rowing, the work you are doing will increase every 2 to 3 minutes. This means that the test will get harder as it goes on. The test will end when you are too tired to continue. This usually takes about 6-12 minutes for most subjects. You may stop the test at any time because you get too tired or because you have other symptoms of discomfort. You may also ask to stop the test at any time for any reason.

Immediately after you stop exercising you will have your peak lactate level measured from a drop of your blood. The blood will be taken using a lancet (small needle) device to prick one of your finger tips then your finger will be placed over a hand held analyzer.

Consent Form Title: FESRT_NIV_consent_Xsect_V4_clean(10_017_17)
IRB Protocol No: 2016P000658 **Sponsor Protocol No: FESRT_NIV_det_pro_V4(09_20_17)**
Consent Form Valid Date: 3/18/2019 **IRB Amendment No: N/A** **Sponsor Amendment No: N/A**
Consent Form Expiration Date: 3/22/2020 **IRB Amendment Approval Date: N/A**

Note: You may be asked to repeat any of the above testing if there is difficulty obtaining results that meet our quality standards or there are equipment issues that arise.

What are the risks and possible discomforts from being in this research study?

General

The measurements of blood pressure, heart rate, and brain blood flow involve the inconvenience and discomfort of multiple attachments to your body, but do not increase risk.

Specific

FES-VO2max Row Test(s)

Some discomfort and feeling of fatigue will be experienced during these tests. There are certain risks associated with these tests. They include abnormal blood pressure responses, fainting, irregular, fast or slow heart rhythm, and in rare instances, heart attack, stroke, or death. There is also a risk of bone or muscle injury during these tests. Every effort has been made to minimize these risks during your health screening. Wearing the facemask connected to the breathing machine during your testing may make you feel lightheaded or short of breath. During all FES-VO2max Row Tests you will be wearing a mouthpiece that may be uncomfortable and may make you feel claustrophobic (feeling afraid of being trapped). Emergency equipment and personnel are available to deal with situations that may arise.

The electrical stimulation used during the FES-row testing can cause a tingling (pins and needles) sensation on the skin or autonomic dysreflexia (signs include: headache, nausea, rise in blood pressure, sweating, and goosebumps). The electrodes that are attached to your skin may also irritate your skin. The electrical stimulation can also cause increases in muscle tightness (spasticity).

Peak Lactate Measurement

Some discomfort will be felt when they insert the lancet into your finger tip. There is the possibility you may experience soreness at the site where the lancet is inserted that day or the days following. There is also a slight chance that you may become dizzy and even faint.

Pulmonary Function Tests

You might feel lightheaded or short of breath after breathing in and out forcefully, and rarely, fainting has occurred after blowing out hard.

What are the possible benefits from being in this research study?

This research may help physicians and scientists to better understand how ventilation effects exercise capacity in spinal cord injury.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

You will not be paid to take part in this research study.

What will I have to pay for if I take part in this research study?

Participation in this study will cost you nothing.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. J. Andrew Taylor, MS, PhD is the person in charge of this research study. You can call him at 617-758-5503 Monday through Friday from 9-5.

If you have questions about the scheduling of appointments or study visits, call Glen Picard at 617-758-5511 .

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers

- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter | Date | Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name | Date | Time (optional)

Consent Form Version: 10/17/2017

Consent Form Title: FESRT_NIV_consent_Xsect_V4_clean(10_017_17)
IRB Protocol No: 2016P000658 **Sponsor Protocol No: FESRT_NIV_det_pro_V4(09_20_17)**
Consent Form Valid Date: 3/18/2019 **IRB Amendment No: N/A** **Sponsor Amendment No: N/A**
Consent Form Expiration Date: 3/22/2020 **IRB Amendment Approval Date: N/A**