Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: August 2016

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

Principal Investigator: J. Andrew Taylor, PhD

Site Principal Investigator:

Description of Subject Population: Adults with spinal cord injury (FES-row-training 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 additionally 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 30 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 3 months to complete this study. You will be required to make 8 testing visits and approximately 36 row training sessions at Spaulding Hospital Cambridge. Your total time commitment will be approximately 44 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-T4. 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.

Study Groups:

This study has two groups. Both groups will participate in FES-row training for 3 months. One group (Breathing Machine Group) will receive positive pressure through a face mask during their exercise training sessions. The other group (Control Group) will receive a "sham" treatment as they will also breathe through a face-mask but will receive much less positive pressure. You will not know which group you are in or what level of positive pressure you are receiving. You will

be "randomized" into one of these two groups. This means that you will be put into a group based on chance alone. Although this process is done with a computer, it is similar to rolling a die to see which group you will belong to. You should be willing to be in either of the treatment groups before you agree to take part in this study.

Study Testing and Training Schedule:

Both the Breathing Machine Group and the Control Group go through all of the same training and testing procedures. The only difference is the Control Group will have positive pressure set much lower than the Breathing Machine Group.

Pre-Rowing Training Evaluation:

- Screening Visit: about 1 hours at Spaulding Cambridge
- FES-VO2max Rowing Test 1: with use of breathing machine
- FES-VO2max Rowing Test 2: without use of breathing machine
- Pulmonary Function Test : (Can be done before a normal training visit)
- Cardiac Output Rowing Test 1: with use of breathing machine
- Cardiac Output Rowing Test 2: without use of breathing machine

FES-Rowing Training:

- FES-Rowing:3 times per week, with breathing machine (30 minutes per session) for 3 months
- Leg Muscle Strengthening: up to 3 times per week at home, on non-rowing days (30 to 60 minutes per session) for 3 months

Three-Month Evaluation:

- FES-VO2max Rowing Test 3: with use of breathing machine
- FES-VO2max Rowing Test 4: without use of breathing machine
- Pulmonary Function Test : (Can be done before a normal training visit)
- Cardiac Output Rowing Test 3: with use of breathing machine
- Cardiac Output Rowing Test 4: without use of breathing machine

Specific Study Details

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

Instructions: You will arrive at the Laboratory between 7:00 and 11:00AM. Do not eat anything for 4 hours before your visit. If you are thirsty during this time, you may drink only water. Do not drink caffeine or alcohol for 24-hours before your visit. Do not take any cold medications for 24 hours before your visit.

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.

Exercise Training, Spaulding Cambridge: (about 30-60 minutes per visit)

The exercise program will consist of FES-row training at Spaulding Cambridge. To be enrolled in this study you must have already been FES-row training for at least 6-months. As in your previous training you will be seated on a rowing machine, sticky pads will be put on the front and back of your thighs. These pads will then be connected to the FES-device that will send an electrical current causing your legs to move. You will also be pulling with your arms. Either you or a staff member will control the electrical stimulation that will make your legs move by pressing a button.

During your FES-row training and FES-row testing you will be breathing through a face-mask. The face mask will be connected to the breathing machine. If you are in the Breathing Machine Group you will be receiving positive pressure through the face mask to try and increase the amount of air you can breathe. If you are in the control group you will also be breathing through a face mask connected to the breathing machine but you will only be receiving minimal positive pressure.

The exercise program will be designed specifically for you by an exercise physiologist and will change as your fitness improves. Your beginning FES-row training exercise plan will be based on your current exercise status. As you become fit you may be able to row at a higher intensity.

We recommend that you perform the FES-rowing training 3 times per week, with a goal of building to 30 minutes per session. We will also ask you to monitor your skin condition, particularly in places that come in contact with the FES-row system. Please report any skin issues to an ExPD staff member before beginning an FES-row strength training or FES-row training session.

There is no minimum requirement for the amount of training or testing that you must attend. We hope you do your best to attend as many of your scheduled sessions as possible. You will be given contact information in case you need to cancel or reschedule an appointment. If you miss a study appointment and we do not hear from you study staff will call you to reschedule and document why you missed your appointment.

You may also continue the seated FES-strength training program at home that was part of your previous FES-row training program. This will be reviewed with you and your program will be tailored to your needs.

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.

Specific Testing Procedures:

FES-VO2max Row Tests, Spaulding Cambridge: (about: 1 hour)
You will perform 2 separate VO2max tests on separate days at the beginning and end of this study. 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.

Cardiac Output Row Test, Spaulding Cambridge: (about: 1 hour)
You will perform 2 Cardiac Output Row tests on separate days at the beginning and end of this study. In one test you will not be using the breathing machine; in the other test you will be using the breathing machine.

The Cardiac Output Row 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 responds to exercise. We hope to find out how much work your heart is doing during exercise. 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. You will need to wear shorts or loose sweat pants for this test**.**

The cardiac output measurement is done by switching the facemask you are breathing in and out of to a re-breathing bag that is already connected to the facemask. Cardiac output is estimated over 3 to 5 breaths as a gas in the bag equilibrates with the air you are breathing in and out. This will be done two times while you are at rest before you begin FES-row exercise and two times while you are FES-rowing. Once you are rowing, you will be asked to try and maintain 80% of the maximal work you did during your FES-VO2max Row Test for about 3-6 minutes. 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.

Pulmonary Function (Breathing) Test, Spaulding Cambridge: (about: 30 minutes)
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.

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.

Cardiac Output 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. During the Cardiac Output Row test you will be wearing a mouthpiece that may be uncomfortable. Breathing in and out of the re-breathing bag may make you feel lightheaded or short of breath. You may also feel claustrophobic (feeling afraid of being trapped) during this test. Emergency equipment and personnel are available to deal with situations that may arise.

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.

Exercise Training Sessions and Leg Muscle Strengthening.
Some discomfort and feeling of fatigue may be experienced during your leg muscle strengthening and exercise training sessions. You may experience some muscle or joint discomfort when beginning an exercise program, exercise training can also result in tendonitis and/or musculoskeletal overuse injuries over time. Wearing the facemask connected to the breathing machine during your training may make you feel lightheaded or short of breath. You may also feel claustrophobic (feeling afraid of being trapped). There are also certain risks associated with exercise. They include abnormal blood pressure responses, fainting, irregular, fast or slow heart rhythm, and in rare instances, heart attack, stroke, or death.

The electrical stimulation used during the FES-row training 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).

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

You will have the opportunity to participate in a supervised exercise program, which may improve your overall fitness and endurance during daily activities as well as decrease your risk of chronic disease.

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 be 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.

Our required policy statement however, stands as follows: "Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs."

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

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 8-4.

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)

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