# Virtual Sailing Simulator in Individuals with Spinal Cord Injury

## IRB#: NA_0044093

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# Johns Hopkins Medicine - eForm A

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## 1. Abstract

*a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.*

The benefits of sport and recreational activities for the disabled are well recognized from the standpoint of health and quality of life. Yet there remains a lack of options for most disabled people, especially the young. Sailing is an attractive sport that can be pursued at recreational and competitive levels. We outline a pilot therapeutic sailing program using the VSail-Access Sailing Simulator system. This program is a good fit with our current Activity Based Restorative therapy practices, and we expect that findings will add to our understanding of recovery from spinal cord injury and how to promote it. Participation in sailing by people with disabilities, particularly in small sailboats, is widely regarded as having positive outcomes on self-esteem and general health for the participants. However, a major hurdle for people with no experience of sailing, even those without disabilities, is the perception that sailing is elitist, expensive and dangerous. Real time "ride on" sailing simulators have the potential to bridge the gap between dry land and on water sailing. They provide a realistic, safe and easily supervised medium, in which non-sailors can easily and systematically learn the required skills before venturing on the water. The task of sailing on a simulator can take place under specified conditions (eg wind strength) and be taught as individual components (e.g. steering, sail trimming) in a way that is not possible on the water where there is a large number of interacting variables. The individual components can then be brought together so that the novice sailor rapidly achieves a degree of competence that would take much longer on the water. The aim of this project is to establish protocols for effective use of a simulator by people with disabilities and then to conduct a pilot trial to test two hypotheses: (1) That the use of the sailing simulator technology enables people with spinal cord injury to learn the skills required to sail on the water in a safe, non-threatening environment; (2) Teaching patients with SCI to sail using simulator technology will provide them with a safe, effective introduction to a healthy, environmentally-friendly, lifelong sport and recreation that will have measurable improvements on their physical health and psychological well-being, including their confidence (self-esteem), morale, and optimism about the future. In this pilot trial 20 subjects with spinal cord injury will be recruited, assessed medically, and with questionnaires to establish baselines for evaluation of quality of life and self-esteem. All subjects will follow a course of instruction leading to mastery of basic sailing techniques such that at the end of the course the subjects will be able to perform a series of standard sailing maneuvers and navigate competently a triangular racecourse on the simulator's display in 12 knots of wind within a preset time. The deliverables will be a detailed protocol for the use of sailing simulators to prepare people with disabilities to start sailing on the water. A secondary deliverable will be a structured protocol for use by sailing centers working with people with disabilities who enter sailing by direct participation on the water. Once the participants have completed the 12 week course they will have the opportunity to sail on the water with the assistance of the Downtown Sailing Club (DSC), Baltimore; however, this is not part of the formal pilot trial, which is aimed primarily at determining the optimum use of a sailing simulator for training purposes. The information from this pilot trial will be used to formulate a future more comprehensive study, which will include a major on water component in collaboration with the Downtown Sailing Club.

Objectives

*b. Include all primary and secondary objectives.*

The objective of this proposed project is to develop an instructional and therapeutic sailing program for spinal cord injured individuals using the VSail-Access system. In the proposed study, we shall test two hypotheses:

**Hypothesis 1:** That the use of the sailing simulator technology enables people with spinal cord injury to learn the skills required to sail on the water in a safe, non-threatening environment.
**Hypothesis 2:** That learning to sail by people with spinal cord injuries to a stage where they are competent to begin to sail on the water in moderate conditions (wind strength up to 12 knots) shows measurable improvements on their physical health, quality of life, morale, self-esteem, and self confidence.

**Specific Aims:**
**Aim 1:** To use novel technology in the form of a real-time physical sailing simulator to enhance the effectiveness of a spinal cord injury rehabilitation program.
**Aim 2:** To investigate what positive outcomes in terms of physical and psychological well-being are demonstrable when a person is using the simulator.
**Aim 3:** To investigate a person's perception of their point of readiness to transition to the water from sailing simulation and how this compares with the therapist's assessment of a person's point of readiness.

**Deliverables**
**1:** A detailed protocol for the use of sailing simulators to prepare people with disabilities to start sailing on the water.
**2:** A structured protocol for use by sailing centers working with people with disabilities who enter sailing by direct participation on the water, rather than via initial sailing simulator experience.

## 2. Background

*a. Briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research.*

Participation in sailing by people with disabilities, particularly in small sailboats is widely regarded as having positive outcomes on the self-esteem and general health of the participants. There is evidence that there are psychological benefits of virtual reality systems for patients in rehabilitation therapy (Chen et al, 2009). In addition, sailing is a family recreational activity; learning to sail will improve family relations and reintegration into the community. For the competitively minded, the worldwide organization Sailability World, Inc. (www.sailability.org) promotes sailing for the disabled. With suitably equipped sailboats, the disabled are able to compete on equal terms with the able-bodied.
Pilot trials in Australia and New Zealand have successfully used this simulation technology to introduce people with severe disabilities to sailing on dry land, with successful transfer to on water competitive and recreational sailing. One patient competed in a World Championship event in July 2010 and qualified for the 2012 Paralympics, less than one year after her initial simulator experience. However, these pilot trials did not assess the impact of the experience of these people, apart from verbal reports of enthusiastic enjoyment of the experience.
Our relationship with the Accessible sailing program at the DSC is significant and is being formalized. The DSC is two miles from Kennedy Krieger Institute. Several of the International Center for Spinal Cord Injury's therapy staff are sailors and also volunteer at the program. Some of our patients have already participated in on-water sailing at that venue. We will include Kennedy Krieger staff coaching sessions given by experienced

DSC staff in the VSail-Access program. This partnership will provide the best available sailing instruction to our subjects and therapists. This will provide insights to the DSC staff on how to improve their own program for spinal cord injured individuals. The relationship will provide continuity for Kennedy Krieger Institute trained sailors transitioning to the water in Baltimore as well as for the family members who will support them. We expect that this continuity will enhance the sailing experience for all and will foster continued participation in the sport.

## 3. Study Procedures

*a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).*

This is a within subject pilot study that plans to enroll 20 chronic (more than 6 months) SCI patients as per recruitment matrix in Table 1. This pilot study will provide preliminary evidence with respect to both Hypothesis 1 and Hypothesis 2 (see above). Organization of a larger trial is planned, the detail design of which will depend upon the outcomes from this study, and subjects will be recruited from individuals already undergoing rehabilitative interventions at the International Center for Spinal Cord Injury (ICSCI) at the Kennedy Krieger Institute and nearby military medical centers (Walter Reed, Baltimore VA). In addition to their already prescribed rehabilitation regimen, the eligible subjects will engage in a virtual reality sailing program (VSail) once a week, 1h/session for 12 weeks. The subjects will be assessed using a battery of physical and neurological indicators before starting the training (baseline), after 6 weeks and 12 weeks of training, and at 6 and 12 months following the completion of the training. During each training visit outcomes will be assessed by the trainer. The study timeline is found in Figure 1.

| | High Tetra (C1-C5) | Low Tetra (C6-C8) | High Para (T1-T6) | Low Para (T7-T12) | Coda Equina (L1-S1) |
|---|---|---|---|---|---|
| Motor Complete (A-B) | 2 | 2 | 2 | 2 | 2 |
| Motor Incomplete (C-D) | 2 | 2 | 2 | 2 | 2 |

Table 1: Recruitment Matrix

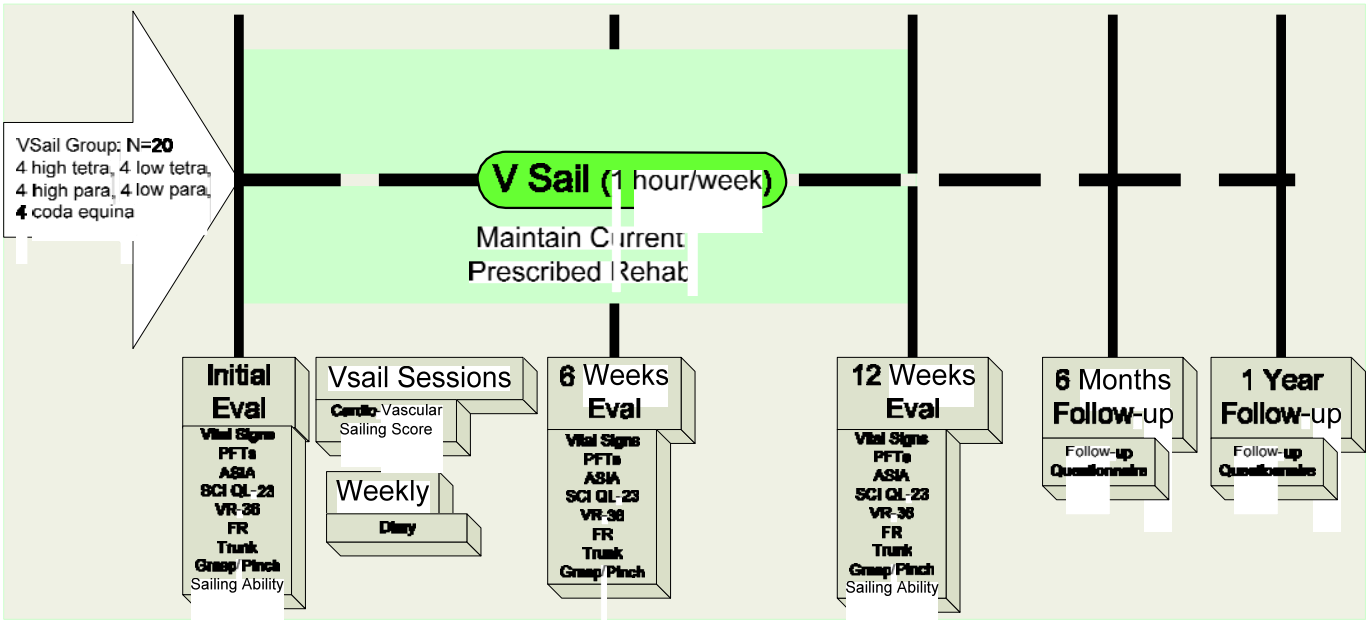


Figure 1: Study Time Line

All activities will be conducted at Kennedy Krieger Institute and are supervised by the Principal Investigator.

**(1) Study Intervention:**

All activities will be conducted at Kennedy Krieger Institute by a VSail trainer.

While undergoing the virtual sailing training, the subjects will use a VSail-Access simulator (Virtual Sailing, Melbourne, Australia). The VSail simulator will be set in the Access Dinghy mode. The VSail sailing parameters will be set to the subjects skill set and progression in the training program: wind speed from minimum (8 knots) to moderate strength (14 knots), pneumatic rams (simulating the heeling of the hull) on or off.

The subjects will be transferred to the VSail cockpit and secured. Following the trainer's instruction, the subject will sail the simulator around virtual courses displayed on a computer screen, using a joystick to control the rudder angle and a mainsheet to control the set of the sail.

Training will be interrupted for fatigue (17 or over on the Rate of Perceived Exertion (RPE) scale), signs and symptoms of Autonomic Dysreflexia (headache, sweating, facial flushing, goose bumps/piloerection, irritability, crying, sudden and profuse sweating above injury level, intense head/neck tingling), symptomatic orthostatic hypotension (dizziness, light headedness, palpitations, sudden vision loss, profuse sweating). Session will resume when symptoms resolve.

All subjects will continue their already prescribed rehabilitation regimen as per clinical plan and indications.

**(2) Study Assessments:**

This pilot study will include a combination of pre- and post-qualitative assessments, as well as 6 and 12 month follow-up. All study assessments will be conducted at Kennedy Krieger Institute by a study team member trained in the assessment. The data collection schedule is in Table 2.

(a)**Vital Signs:** This is a routine test performed for people with spinal cord injury. Resting heart rate and blood pressure in sitting position. This test will be performed on all subjects.

(b)**Pulmonary Function Test (PFTs):** This is a routine test performed for people with spinal cord injury. Three respiratory functions will be measured: Vital Capacity (VC) is the maximal amount of air that can be exhaled after a maximal inhalation; Negative Inspiratory Force (NIF) is the ability to take a deep breath in and to generate a cough strong enough to clear secretions; Peak Cough Flow (PCF) measures the expiratory muscle force and the ability to cough. This test will be performed on all subjects.

(c)**ASIA Test:** This is a routine test performed for people with spinal cord injury. The ASIA (American Spinal Injury Association) exam assesses motor function at 10 key muscles in the body and light touch and pinprick sensation at 28 key points on each side of the body. It is also used to classify injury level and severity. This test will be performed on all subjects.

(d)**Spinal Cord Injury Quality of Life Questionnaire (SCI QL-23):** This is a routine test performed for people with spinal cord injury. The SCI QL-23 is a 23-item health-related quality of life questionnaire (weighted scale, aggregate score: GQOL: overall rating of life situation; FUNC: physical and social limitations; DEPR: distress and depressive feelings; PROB: perceived loss of independence and other issues relating to injury [Copyright © 1990 Health Care Research Unit, Sahlgrenska University Hospital, Sweden]). The subject will read the questionnaire and answer the questions; if needed ,assistance will be provided to record the answers on the form. The SCI QL-23 questionnaire will be used for all subjects.

(e)**Veterans RAND 36-Item Health Survey (VR-36):** This is a routine test performed for people with health related issues. The VR-36 is a health-related quality of life questionnaire (weighted scale, aggregate score [Copyright © Boston University School of Public Health, MA]. The subject will read the questionnaire and answer the questions; if needed, assistance will be provided to record the answers on the form. The VR-36 questionnaire will be used for all subjects.

(f)**Functional Reach (FR) Test:** This is a routine test performed for people with spinal cord injury. This test is used to evaluate trunk balance. This test is performed by patient reaching forward as far as they can while seated in their wheelchair. The distance traveled by the top of the reference shoulder is measured; 2 practice trials and 1 actual reach test is performed for the purpose of the study. The forward and lateral reach will be assessed on all subjects.

(g)**Level of Trunk Activation:** This is a routine test performed for people with spinal cord injury. This test will assess the activation of trunk muscle by asking the patient to perform a sit-up from the supine position. Using landmarks such as sterna angle, nipple line, supra-sternal notch, and ribs the lowest level of trunk activation will be determined. This test will be performed on all subjects.

(h)**Grasp/Pinch Testing:** This is a routine test performed for people with spinal cord injury. This is a standard test used to assess strength of grasp and lateral pinch. The Jamar dynamometer will be used to assess grasp and lateral pinch. This test will be performed on all subjects.

(i)**Sailing Ability Questionnaire:** This is a routine test performed for people involved in a training program. This questionnaire will assess the subject's views about sailing, as well as the subject's perceived sailing abilities. This questionnaire will be used for all subjects.

(j)**Cardio-Vascular Monitoring:** This is a routine test performed for people undergoing a cardio-vascular type exercise. This test will be performed on all subjects. The following vital sign will be recorded:

- Fatigue as per RPE.
- Blood pressure and heart rate with any sign or symptom of autonomic dysreflexia (AD) (manifested as pilo-erection, sudden and profuse sweating above injury level, facial flushing, intense head/neck tingling, headache) or signs of orthostatic hypotension (dizziness, light headedness, palpitations, sudden vision loss, profuse sweating).

(k)**Sailing Score:** This is a routine function of the VSail-Access simulator. The score will be based on the ability to perform specific sailing maneuvers (steering predetermined courses, sail trimming, tacking, gybing, mark rounding), and the ability to navigate a simple course around marker buoys (triangular configuration) on the computer screen within a predetermined time. This test will be performed on all subjects.

(l)**Weekly Diary:** This is a routine test performed for people in a clinical study. A weekly diary will be kept by the subject. The following events will be recorded: change in medical status, change in medication, change in prescribed rehab program. The study coordinator will review the diary with the subject every week. This will be done for all subjects.

(m)**Follow-up Questionnaire:** This is a routine test performed for people involved in a training program. This questionnaire will assess the subject's views about sailing on the water after been in the VSail training program, as well as the subject's perceived sailing abilities.. This questionnaire will be used for all subjects.

*b. Study duration and number of study visits required of research participants.*

The study will last one (1) year, with an active training phase of 12 weeks. The subjects will continue their already prescribed treatment rehabilitation regiment, and attend one hour session of virtual reality sailing once a week for 12 weeks. They will return at 6 and 12 months to be assessed. The study timeline is found in Figure 1 and the data collection schedule in Table 2.

| | Initial | Training | Weekly | 6 Weeks | 12 Weeks | 6 Months | 12 Months |
|---|---|---|---|---|---|---|---|
| | 2 hours | 1 hours | 10 minutes | 2 hours | 2 hours | 10 minutes | 10 minutes |
| Vital Signs | √ | | | √ | √ | | |
| PFTs | √ | | | √ | √ | | |
| ASIA | √ | | | √ | √ | | |
| SCI QL-23 | √ | | | √ | √ | | |
| VR-36 | √ | | | √ | √ | | |
| Functional Reach | √ | | | √ | √ | | |
| Trunk | √ | | | √ | √ | | |
| Grasp/Pinch | √ | | | √ | √ | | |
| Sailing Ability | √ | | | | √ | | |
| Cardio-Vascular | | √ | | | | | |
| Sailing Score | | √ | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Diary | | | √ | | | | |
| Follow-up Q | | | | | | √ | √ |

Table 2: Data Collection Schedule

The following assessments will be performed at the Initial, and 12 Week visits:

(a) Vital Signs (about 5 mins)
(b) Pulmonary Function Test (about 5 mins)
(c) ASIA (60 mins)
(d) SCI QL-23 (about 10 mins)
(e) VR-36 (about 10 mins)
(f) Functional Reach Test (about 5 mins)
(g) Level of Trunk Activation (about 5 mins)
(h) Grasp/Pinch test (about 5 mins)
(i) Sailing Ability Questionnaire (about 5 mins)

The following assessments will be performed at the 6 Week visits:

(a) Vital Signs (about 5 mins)
(b) Pulmonary Function Test (about 5 mins)
(c) ASIA (60 mins)
(d) SCI QL-23 (about 10 mins)
(e) VR-36 (about 10 mins)
(f) Functional Reach Test (about 5 mins)
(g) Level of Trunk Activation (about 5 mins)
(h) Grasp/Pinch test (about 5 mins)

The following assessments will be performed at all VSail training Visits:

(j) Cardio-Vascular Monitoring (about additional 5 minutes to VSail session)
(k) Sailing Score (about 5 minutes included in VSail session)

The following assessments will be performed weekly during the training:

(l) Weekly Diary review (about 10 minutes), once a week only

The following assessments will be performed at the 6 Month and 12 Month visits:

(m) ) Follow-up Questionnaire (about 10 mins)

*c. Blinding, including justification for blinding or not blinding the trial, if applicable.*

Not Applicable.

*d. Justification of why participants will not receive routine care or will have current therapy stopped.*

All subjects will continue to consistently perform their usual ("baseline") amount of physical activity throughout the study, including clinic and home exercise program. "Baseline" activity is defined as amount of physical activity performed for at least 1 month prior to enrollment. Routine care will not be interrupted.

*e. Justification for inclusion of a placebo or non-treatment group.*

Not Applicable.

*f. Definition of treatment failure or participant removal criteria.*

Subjects may withdraw from the study at any time for any reason.

The subject may be removed from the study for any of the following reasons:

a. The subject experiences a medical emergency that necessitates discontinuation of therapy
b. The subject experiences a serious adverse event that is judged to be likely related to the therapy or is of severity that warrants discontinuation of treatment.
c. For any medical reason at the discretion of the investigator.
d. Subject is no compliant: participants who miss more than 3 sessions of training for the duration of the study.

*g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.*

Upon completion of the study, participants will be referred back to their treating SCI specialist who will be made aware of the treatment and follow-up. The same protocol will be followed for patients who terminate the study early. In the event of discontinuation due to adverse event, participants will be followed by the PI until resolution or stabilization of their adverse condition and then referred back to their treating SCI specialist.

Inclusion/Exclusion Criteria

*h. Inclusion:*

a. Males and Females, age 18-75, all ethnic groups.
b. Spinal Cord Injury.
c. Chronic injury, > 6 months from the injury.
d. All ASIA neurological levels (C1-S1) as per Table 1.
e. All ASIA impairment scale A-D as per Table 1.
f. Subjects are able to comply with procedures and follow-up.
g. Subjects are medically stable, with no recent (1 month or less) inpatient admission for acute medical or surgical issues.

*i. Exclusion:*

a. Cardiovascular disease as defined by previous myocardial infarction, unstable angina, requirement for anti platelet agents, congestive heart failure, or stroke NYHA Class III or IV, history of arrhythmia with hemodynamic instability.
b. Uncontrolled hypertension (resting systolic BP > 160mmHg, or diastolic BP > 100mmHg consistently).
c. Severe hypotension (systolic BP < 80 mmHg, or diastolic BP < 55 mmHg).
d. Ventilator dependant subjects.
e. Significant cognitive impairment.
f. History of epileptic seizures.
g. Unstable long bone fractures of the extremities.
h. Subjects having Stage III or greater skin ulcerations.
i. Active sailor.
j. Active drug or alcohol use or dependence that, in the opinion of the site investigator, would interfere with adherence to study requirements.

## 4. Drugs/ Substances/ Devices

*a. The rationale for choosing the drug and dose or for choosing the device to be used.*

The VSail-Access simulator (Virtual Sailing, Melbourne, Australia) is the first sailing simulator available for people with disabilities.

The VSail simulator is a generic sailboat cockpit powered by a pneumatic ram and custom designed software. The sailor sails the simulator around virtual courses displayed on a computer screen or overhead display in the same way as a real sailboat on water (a tiller to control the rudder angle, a mainsheet to control the set of the sail and body position to control heeling of the hull). Electronic sensors provide real time feedback to match the movements of the virtual sailboat displayed on the screen with those of the simulator. Sailors can select wind strength and conditions to suit their ability. The VSail-Access simulator is a variation on the VSail where the cockpit is fitted with a seat based on the design used for Access dinghies (http://accessdinghy.org).

*b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.*

Not applicable.

*c. Justification and safety information if non-FDA approved drugs without an IND will be administered.*

Not applicable.

## 5. Study Statistics

*a. Primary outcome variable.*

(1) Ability to sail:
(a) standard maneuvers: ability to perform specific sailing maneuvers (steering predetermined courses, sail trimming, tacking, gybing, mark rounding).
(b) Ability to navigate a simple course around marker buoys (triangular configuration) on the computer screen within preset time.
(2) Quantitative health, welfare, self esteem and quality of life survey.

*b. Secondary outcome variables.*

(1) ASIA (American Spinal Injury Association) scoring.
(2) Cardio vascular health (pulmonary function test, vital signs).
(3) Trunk control (functional testing of reach, level of trunk muscle activation).
(4) Grip and pinch strength.

*c. Statistical plan including sample size justification and interim data analysis.*

This is a pilot study. No statistical analysis is planned.

*d. Early stopping rules.*

This is a pilot study. No early stopping rules have been set. Subject will be removed from the study as per treatment failure or removal criteria listed in section 3.f.

## 6. Risks

*a. Medical risks, listing all procedures, their major and minor risks and expected frequency.*

The medical risks are defined in the section below. This allows combining the risk and risk management in the same section for each risk.

*b. Steps taken to minimize the risks.*

All assessments and intervention sessions will be supervised by the Principal Investigator.

For all the study procedures, the risks and risk management are defined in the sections below.

### (1) Intervention Risks:

**VSail:**

There is a minimal risk of pressure sores, and skin break down. **To further minimize the risk**, the subject seating in the VSail will be assessed and necessary precautions will be taken and proper protection equipment (gloves) will be used.

There is a minimal risk of falls during transfers in/out of the VSail. **To minimize the risk**, subjects will be transferred using standard transfer procedures that are in use clinically at the ICSCI.

There is a minimal risk of fatigue, autonomic dysreflexia, or orthostatic hypotension. **To minimize the risk**, subjects are actively monitored during VSail training as described above (**(j) Cardio-Vascular Monitoring**), by a study team member trained in the procedure.

**(2) Assessment Risks:**

**Vital Signs:** There are no known risks associated with this measurement.

**Pulmonary Function Test (PFTs):** The risk is minimal for most people. Since the test involves some forced breathing and rapid breathing, patients may have some temporary shortness of breath or light-headedness. Patients breathe through a tight-fitting mouthpiece, and will have nose clips. To **minimize the risk**, a study team member trained in the procedure will perform the test.

**ASIA test:** There is a risk of discomfort at the site of the pin prick during the ASIA Exam. To **minimize the risk**, a study team member trained in the procedure will perform the ASIA exam.

**Spinal Cord Injury Quality of Life Questionnaire (SCI QL-23):** Aside from the risk associated with disclosing personnel or protected health information outside the research study, there are no known risks associated with this measurement.

**Veterans RAND 36-Item Health Survey (VR-36):** Aside from the risk associated with disclosing personnel or protected health information outside the research study, there are no known risks associated with this measurement.

**Functional Reach (FR) test:** Patients may feel anxiety related to loss of balance. To **minimize the risk**, a study team member trained in the procedure will perform the test and will position themselves in the direction of the lean so subject does not fall.

**Level of Trunk Activation:** Patients may feel anxiety related to loss of balance. To **minimize the risk**, a study team member trained in the procedure will perform the test.

**Grasp/Pinch Testing:** There are no known risks associated with this measurement.

**Sailing Ability Questionnaire:** Aside from the risk associated with disclosing personnel or protected health information outside the research study, there are no known risks associated with this measurement.

**Cardio-Vascular Monitoring:** This is a vital signs measurement. There are no known risks associated with this measurement.

**Sailing Score:** There are no known risks associated with this measurement.

**Weekly Diary:** Aside from the risk associated with disclosing personnel or protected health information outside the research study, there are no known risks associated with this measurement.

**Follow-up Questionnaire:** Aside from the risk associated with disclosing personnel or protected health information outside the research study, there are no known risks associated with this measurement.

**(3) Other Risks:**

**Time Commitment:** The time commitment for the training over the 12 weeks may be inconvenient, as well as the follow-up. **To minimize the risks**: 1] The subject will be asked to contact the study coordinator if having problems scheduling the visits; 2] If we feel that the subject can not commit the time and effort, he/she will be excluded from the study; 3] The visits may cause moderate social, school and work disruption. The start of the study will be scheduled to lessen those disruptions; 4] the follow-up questionnaire can be mailed to the subject or done over the phone.

*c. Plan for reporting unanticipated problems or study deviations.*

Adverse events, unanticipated problems and/or study deviations will be reported in writing by the Principal Investigator to the JHM-IRB and KKI Office of Research Compliance.

*d. Legal risks such as the risks that would be associated with breach of confidentiality.*

There are minimal legal risks associated with breach of confidentiality for this study. To minimize the risk of breach of confidentiality, access to participant/study data will be limited to study team members only. All study data will be stored in a department al locked cabinet and secure database program.

*e. Financial risks to the participants.*

There will be no financial risks to the subject for any of the study tests.

Any complications that arise from any study related injury will be billed to the patients insurance. If the study participant has health insurance, the costs for any treatment or hospital care received as the result of a study-related injury will be billed to their health insurer. Any costs that are not paid for by the health insurer will be billed to the patient. If the study participant does not have health insurance, he or she will be billed for the costs of any treatment or hospital care received as the result of a study-related injury.
Subjects will be responsible for the cost of travel to and from the Institute, as well as any food/meals purchased throughout the day while engaged in study procedures. Valet parking is available at no cost.

## 7. Benefits

*a. Description of the probable benefits for the participant and for society.*

There are no known benefits for those who participate in this study.

## 8. Payment and Remuneration

*a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.*

No monetary compensation will be provided. There will be no penalty for failure to complete the protocol.

## 9. Costs

*a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.*

There is no cost to study participants for any of the study tests. Subjects will be responsible for the cost of travel to and from the Institute (Valet parking is available at no cost to study participant), as well as any food/meals purchased throughout the day while engaged in study procedures.