VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM
Version Date: September 11, 2017	**Page: 1 of 10**
Subject Name:	**Informed Consent Date:**
Principal Investigator: Ann M. Spungen	**VAMC: James J Peters**
Title of Study: Evaluation of an upright powered wheelchair for people with SCI	

1. Purpose of study and how long it will last:

You are being asked to participate in a research study. The purpose of this study is to learn if the upright powered wheelchair that is being studied (UPnRIDE) is usable by the participants, if there is device satisfaction with its use, if there are obstacles that are difficult or prevent use, and to determine if there are any health-related benefits associated with being upright in this type of wheelchair. You are eligible for screening because you have spinal cord injury and you are not able to stand or walk. If you qualify for participation in this study, you will be placed in this device and your legs, hips and trunk will be strapped in for support. You will be taught to control a joystick that is used to signal the device to lift you to a standing position and you will be taught to drive it with a joystick indoors and outdoors. This study has 5 time points sections: 1) pre-testing evaluations (1-2 visits); 2) the first set of training sessions (18 sessions in 6 weeks); 3) mid-point evaluations (1-2 visits); 4) the second set of training sessions (an additional 18 sessions in 6 weeks); 5) post testing evaluations (1-2 visits). The total time required to participate in this study is 14 weeks. We plan to complete 20 participants with spinal cord injury for this study.

The electrical and mechanical safety properties of the UPnRIDE have been tested and have passed the internationally accepted standards for electrically powered wheelchairs, scooters and their chargers. The safety tests include static and dynamic stability in use, strength and durability, electrical safety and electromagnetic compatibility, driving performance, braking distance etc. This study is being sponsored by the company, UPnRIDE Robotics Ltd.

Inclusion Criteria:

1. Power wheelchair user as a primary means of mobility;
2. 18-89 years old;
3. ≥1 year after SCI;
4. Height of 160 to 190 cm;
5. Weight of <100 kg; and
6. Able to sign informed consent.

Exclusion Criteria:

1. Able to ambulate with or without an assistive device or physical assistance greater than 4 consecutive steps;
2. Any pressure ulcer at any body location that is deemed to be contraindicated for a power wheelchair or standing frame by the study physician;
3. Concurrent medical disease that would be exclusionary for standing (as per the clinical

judgment of the study physician);
4. Severe spasticity (Ashworth 4) or uncontrolled clonus;
5. History of fragility fractures, long bone fractures in the past 1 years, heterotrophic ossification, or other bone conditions that would be exclusionary for use of a standing modality as per the clinical judgement of the study physician;
6. Significant contractures that would be exclusionary for use of a standing modality as per the clinical judgement of the study physician
7. Psychiatric or cognitive status that may interfere with the ability to follow instruction to use the device; and
8. Pregnant or lactating women.

2. Description of the Study Including Procedures to be Used:

If you consent to participate in this research study, you will be asked to visit Room 7A-13 at the James J. Peters VAMC and the following procedures will occur:

Screening Evaluations:

A History, Physical Examination: This examination will be performed by the study physician to check your overall health and history and make sure you do not have any medical problems that are contraindicated for participating in this study. This exam will be performed once for screening purpose.

International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI): A test of your sensory function and strength at key levels above and below your spinal injury. This exam will be performed two times: at baseline and post.

Ashworth Spasticity Scale: The Modified Ashworth Scale will be used to assess spasticity of the lower limbs. This exam will be performed two times: at baseline and post.

Testing Sessions:

Postural orthostatic hypotension blood pressure tolerance test (OH BP): You will be in the supine position on a bed or elevated gym mat and beat-to-beat heart rate (HR) will be recorded every 60 seconds for 10 minutes, followed by passive re-positioning to the seated position on a bed or elevated gym mat with the hip and knee at a 90° angle and the lower leg hanging off the side. Passive repositioning will be accomplished by one staff member lifting your torso by the shoulders, while supporting the head and neck, and a second staff member shifting you perpendicular to the bed and allowing your legs to hang off the side. You will be instructed not

to assist in the passive movement during this transition, and will be supported by staff. It will be performed three times: at baseline, midpoint and post.

Body Composition: A dual energy x-ray absorptiometry (DXA) scan for regional and total body fat, lean and bone tissue masses will be performed. You will be asked to lie on a padded tabletop. A machine will use a very low dose radiation which will tell us the amount of muscle, fat and bone you have in your body. The maximum radiation you will be exposed to for each scan is as follows:

Scan Type	Entrance Dose	Effective Dose	Scan Time
Total Body	6 µGy	8.62 µSv	739 sec
Dual Femur DXA	329 µGy	12.3 µGy	212 sec
Knee DXA	34 µGy	no data	54 sec

We estimate all of these DXA measurements combined will sum up to less than 35 µSv of absorbed radiation. This measurement is minimal even when compared to a routine chest x-ray which has an approximate dose of 60 µSv. In addition the average person in New York City receives approximately 3000 µSv/year. Therefore you would have to have all these tests done 100 times to receive an equivalent dose. You will be asked to do this procedure once during the screening evaluation. This exam will be performed two times: at baseline and post.

Bowel function surveys: You will be asked questions about your bowel function and management. These surveys will be performed three times: at baseline, midpoint and post.

SCI-QOL: The Spinal Cord Injury Quality of Life measurement tool will be performed three times: at baseline, midpoint, and post.

Blood draw: Ten ml (2.03 teaspoons) of blood will be drawn and divided into different tubes for analysis. The analyses will be to determine blood levels of insulin, glucose, cholesterol, hormones, proteins, and inflammatory markers. The cholesterol levels will be measured by Quest diagnostics, Inc., Teterboro, NJ and inflammatory markers by Dr. Ona Bloom, at The Feinstein Institute for Medical Research, Manhasset, NY. The samples of your blood will be sent to both outside laboratories in transfer tubes that will be labeled only with a participant ID number and study time point. All other blood sample analyses will be done in the core lab of our research center at the VA hospital. Ten ml of blood will be collected 3 times (pre, mid, post) over the course of the study.

Training Sessions: You will be asked to participate in UPnRIDE approximately 3.5 hours per session, 3 times per week for 12 weeks. During each 3.5-hour session, you will be asked to stand at least 5 minutes during every 15 minutes or more as tolerated. One time each session, you will be asked to perform the Activities of Daily Living courses. During each session, heart

rate (HR), blood pressure (BP), total session time, time in standing posture, count of sit-to-stand positioning, total distance of movement, and rating of perceived exertion (Borg scale) for mobility skills will be monitored. At all study visits during the training period, you will be asked to answer general health questions about the occurrence of any pressure ulcers or infections. Pulmonary function tests and blood flow will be performed at the first and last sessions.

Pulmonary function test and Breathing pattern assessment:

Pulmonary function testing will be assessed at sessions 1 and 36. You will be asked to breath in and out of machines that can measure the amount of air from your lungs that passes through them. You will have a nose clip on your nose and will be breathing through a mouthpiece. Sometimes you will be asked to breathe normally and at other times you will be asked to inhale and exhale as forcefully as you possibly can. This test will tell us how much volume of air your lungs can hold and what forces of pressure you are able to generate with your lungs. During one of the tests, you will be given 100% oxygen and asked to breathe it in and out for about 3 to 6 breaths. This test allows us to measure the amount of air in your lungs that cannot be exhaled.

Breathing pattern will be assessed at sessions 1 and 36: You will be asked to wear two chest straps for the full session and for a 3-hour period while just sitting in your usual wheelchair. These straps are able to measure each time you breathe in and out, or take a sigh.

All pulmonary function and breathing pattern tests will be performed while in the seated and standing positions in the UPnRIDE. Note, this is especially interesting because due to the limited ability to position a person with motor complete spinal cord injury in a standing position (only a tilt table has been used in the past and in very few subjects), there is very little known about the effect of standing posture on pulmonary function in persons with SCI.

Blood flow:

Lower extremity blood flow will be measured at sessions 1 and 36 by placing a thin cable around your legs (called a strain gauge plethysmography). You will barely notice the cable around your legs. This measurement will inform us about any collection of extra blood that may be occurring in your legs while you are standing in the UPnRIDE.

3. Description of any Procedures that may Result in Discomfort or Inconvenience:

- When you first stand up you may experience some dizziness, become lightheaded or faint because you are not used to standing. Study team members will be by your side while you use the UPnRIDE.
- During the training, you may experience an increased rate of breathing (shortness of breath), dizziness, and chest pain or potentially an irregular heartbeat. If you experience any chest pain or irregular heartbeats during training, you will make the study physician aware and the test will be stopped immediately. During this portion of the study you may

also experience muscle and joint aches, joint sprain, blood pressure variations, skin abrasions, swelling or bruising due to rubbing from the straps in the UPnRIDE or while in a harness that supports your body weight. You may also bruise due to manual contact or due to braces worn on the lower limbs. You are being asked to participate in a study that requires a strong commitment of your time. In order for us to effectively test the utility of the UPnRIDE the number and frequency of the sessions are needed. If you miss more than 80% of your training sessions we may consider removing you from the study.

- If you are a woman of child bearing age we must be sure that you are not pregnant or planning to become pregnant to participate in this study. This research may have unknown effects on an unborn child and should not be done during pregnancy. It is necessary for a pregnancy test to be done first. To your knowledge you are not pregnant at the present time. You also agree to avoid becoming pregnant (use contraceptives, take precautions against becoming pregnant, etc.) during this study.
- The discomfort of a blood draw include the possibility of a bruise or infection at the site of skin puncture, temporary faintness and rarely, temporary loss of consciousness due to vasomotor instability (i.e. the blood vessels reflexively swell resulting in a fall in blood pressure which is commonly called "vasovagal episode").

4. Expected Risks of Study:

- A DXA scan carries a small risk associated with low levels of radiation used in the scan. The total amount of radiation exposure from the DXA is approximately 1/5th to 1/10th of that received from a routine chest x-ray.
- The risks of blood draw include the possibility of a bruise or infection at the site of skin puncture, temporary faintness and rarely temporary loss of consciousness due to vasomotor instability (i.e., the blood vessels reflexively swell resulting in a fall in blood pressure which is commonly called "vasovagal episode").
- During the training, you may experience an increased rate of breathing (shortness of breath), dizziness, and chest pain or potentially an irregular heartbeat. If you experience any chest pain or irregular heartbeats during this time, you will make the study staff aware and the test will be stopped immediately. During this portion of the study you may also experience muscle and joint aches, joint sprain, broken bones, blood pressure variations, skin abrasions, swelling or bruising due to rubbing while the harness supports your body weight. You may also bruise due to manual contact or due to braces worn on the lower limbs.
- A small, but possible risk associated with testing the UPnRIDE is that it may be pushed over by an unforeseen force or tipped over by traversing an unseen object. The potential of

this occurring is greatly minimized because the device has passed high standards in mechanical testing. Additionally, by having study staff that are fully trained on the limitations of the UPnRIDE, this fall risk will be minimized. You will be taught these limitations and expected to adhere to them as well. The risk of a fall from the UPnRIDE is no greater than the risk of a fall from other standing wheelchairs.

- While the risk of a broken bone is small, it is important to understand that people with spinal cord injury are at risk of having fragile bones from the paralysis. Therefore, there is a small risk when moving from sit to stand, stand to sit or from weight bearing while standing of having a fragility fracture. Other possible risks include discomfort, triggered spasm, reflex bowel or bladder activity, skin pressure/friction or autonomic instability during use of the device. Lastly, the device itself could malfunction.

To minimize the above risks the following precautions will be taken:

1. The study team members will be trained by representatives from the manufacturer.
2. Your medical chart will be reviewed. You will also be examined by the study team physician (who is also a Staff SCI Physician) before being cleared for participation.
3. To prevent tripping over any obstacles, the areas used for performing the activities will be checked before and during each session to be free of any obstacles.
4. You will never be left unattended when using the UPnRIDE during a session.
5. HR and BP will be monitored throughout the sessions.
6. The power source of the system will be supplied with a fully charged battery and a back-up battery.
7. You will be examined on the system contact points for skin redness, irritation or breakdown before and after each session. If evidence of skin redness, irritation or breakdown exists, alternate placements for straps and/or padding will be used to protect the area. Participants who have continued breakdown will be temporarily discontinued.
8. You will be checked after each session for signs of swelling. If present, you will be instructed to elevate your feet, possibly use compression socks for the next session(s), and/or reduce the upright time or training frequency. If swelling persists, you will be referred to your primary care physician. Training sessions will be discontinued if need be.
9. People with a fragility fracture history will be excluded.
10. Upon completion of the study, you will not have access to this device. If you develop feelings of sadness or become depressed after completion, tell a member of the study team and they will assist you in finding care.

There also may be risks and discomforts that cannot be foreseen.

5. Expected Benefits of the Study:

There may be no direct benefit to you from this study. But, any information we learn from this study may help others with spinal cord injury. There are possible benefits by taking part in this study such as you may feel healthier and happier because of regaining an ability to be upright. The health-related benefits of standing are unknown at this time.

6. Other Treatments Available:

This study is being done for research purposes, no clinical care or rehabilitation therapy that you are scheduled for will be withheld from you. As such, there are no other treatments available in place of the UPnRIDE wheelchair. Please note: The UPnRIDE is not a cure for paralysis; it is an external device that permits you to stand.

7. Use of Research Results:

We will let you and your physician know of any significant new findings made during this study which may affect your willingness to participate in this study. All research material generated from the study will remain in the possession of Dr. Ann M. Spungen and her study team. Only study team members will have access to the research materials obtained from you for this study. Coded physical materials will be secured in a locked file cabinet behind locked doors at the James J. Peters VAMC. Electronic data without your name or other identifying information will be stored on secured VA networks, behind VA electronic security systems, in access-restricted folders. Your identifiable and personnel health information (PHI) will be protected by coding your identity. Only the study team members will have access to the code.

We may ask to video record you for the purposes of viewing yourself to help improve your abilities. If you do not wish to be video recorded we will not do so. In some instances, we may ask to use your video recordings at various presentations. A separate waiver will be presented to you at that time for you to give permission for use of any video recordings of you during your training sessions.

□_____ By checking this box and initialing, you agree to be contacted by the Principal Investigator or her investigative team at a future date for additional studies being conducted in the Center for the Medical Consequences of SCI.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

Your medical records will be maintained according to this medical center's requirements and all electronic and hardcopy Research Records are currently not scheduled for destruction and will not be destroyed.
All specimens obtained during this study will be stored in the Basic Science Laboratory at The Center on the Medical Consequences of Spinal Cord Injury located at the James J. Peters Veterans Affairs Medical Center, Bronx, NY.

In order to comply with federal regulations, research records identifying you may be reviewed by the following: Representatives of the sponsor or sponsors [Department of Defense, Authorized representatives of the Bronx VAMC (e.g. Institutional Review Board, Research Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), Food and Drug Administration (FDA), and the Office for Human Research Protections (OHRP).

Because this research involves articles regulated by the FDA, the FDA may choose to inspect and copy medical or research records that identify individual research subjects. If this study was initiated on or after March 7, 2012, 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 a summary of the results. You can search this web site at any time.

8. Compensation and/or Treatment in the Event of Injury:
The VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Further information about compensation and medical treatment may be obtained from the medical administration service at this VA medical center.

9. Voluntary Participation:
You are not required to take part in this study; your participation is entirely voluntary you can refuse to participate in this study or withdraw your participation in this study after you consent without penalty or loss of VA or other benefits to which you are entitled.

10. Termination of Participation:
You may decline to participate now or you can withdraw from the study at any time after signing consent. If you decline to participate or withdraw, your regular medical treatment will not be interrupted or withheld. If you decide to withdraw from the study at a later date, you will sign a form to revoke your previous authorization. If you decide to withdraw from this research study

please notify us. This will not interfere with your regular medical treatment, if you are a patient. If you miss more than 80% of your sessions, your participation may be terminated by the investigator without regard to your consent.

11. Costs and Reimbursements:

As a Veteran or non-Veteran, you will not be charged for any treatments or procedures that are part of this study. For veterans who are required to pay co-payments for medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study.

You will receive $20 per visit for 36 visits and $75 per testing day for 3 visits to help defray the costs of travel. The total payment over 39 visits is $945. Payments will be direct deposited into your bank account. It typically takes 6-8 weeks for payment to arrive.

12. Contact Person(s):

(a) To obtain answers to questions about the research, report or seek treatment for a research-related injury, or to voice concerns or complaints about the research contact the following (investigator/research team):

- During the Day: **Dr. Ann M. Spungen, 718-584-9000, x5814 or x5420**
- After Hours: **The SCI Physician on call, 718-584-9000, "0" for operator**

(b) To voice concerns or complaints about the research from someone outside of the research team, contact the following:

I understand that should I wish to discuss my participation in this study with any other doctor or layperson, I can contact Mary Sano, Ph.D. ACOS/R&D Program by requesting an appointment at (718) 741-4228 hospital extension 4228, first floor in the research building, room 1F-01 If I have questions, concerns and/or complaints or to offer input, I can ask one of the researchers listed above or contact **Dr. Sano**. Medical problems during the course of the study should be addressed to the investigator at the phone listed above.

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above.

Dr. Ann M. Spungen or his/her delegate has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.
This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

Subject Signature	Date	Time

Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page)	Signature of Person Obtaining Informed Consent	Date