

Informed Consent Form SCI User

Official Study Title: Empowering mobility in people with Spinal Cord Injury with a hands free self-balancing personal exoskeleton

NCT number: NCT06777576

Document date: 08/11/2025



Participant Name:

Date:

Title of Study: Empowering mobility in people with Spinal Cord Injury with a hands-free, self-balancing personal exoskeleton

Principal Investigator: Ann M. Spungen, EdD VA Facility: James J Peters VA Medical Center

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by Wandercraft SAS. This research study is being performed at the James J. Peters Veterans Affairs Medical Center (JJPVAMC) and at the Kessler Foundation (KF). JJPVAMC and Kessler are separate institutions and independent of one another. No data or information will be shared between the two sites. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This study aims to show that the Eve robotic walking device is safe and can be properly used by people with spinal cord injury (SCI), with a companion, to help them. The device, developed by Wandercraft, is a new type of robotic exoskeleton device, offering powered support to stand and walk again, without needing crutches or a walker. It can be used by people with higher-level SCI, who have limited hand function, thanks to a specially designed remote and trunk support. The Eve device is a new version of Wandercraft's Atalante X exoskeleton, already available in the US for rehabilitation, and with the data collected in this study, it will serve as a basis to seek approval for the sale of the Eve device in the US.

By doing this study, we hope to learn that the device is safe and easy to learn by people with SCI and a companion to help them. Your participation in this research will consist of up to 10 visits 1-3 hours long.

The purpose of this research is to gather information on the safety and effectiveness of the Eve device made by Wandercraft SAS.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The main benefits of this study include the chance to use a walking exoskeleton device that will allow the user to do activities not possible in a wheelchair. *For a complete description of benefits, refer to the Detailed Information section of this form.*

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The main risks of this study are those that come from being upright and walking. These include the chance of injury from falling or being upright. *For a complete description of risks, refer to the Detailed Information section of this form and/or Appendix.*

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There are other exoskeletons on the market that are approved for home or institutional (for example, physical therapy) *For a complete description of alternate treatment/procedures, refer to the Detailed Information section of this consent.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Ann M. Spungen, EdD (Principal Investigator), at the James J. Peters VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is:

- During the Day: Ann Spungen, EdD at 718-584-9000 ext. 5814
- After Hours: Ann Spungen, EdD at 347-971-0413

DETAILED INFORMATION ABOUT THE STUDY

INCLUSION CRITERIA

1. Any gender, age 18 years or older
2. Motor complete or incomplete SCI with lesions at or above T6
3. ≥ 6 months post SCI
4. Able and willing to attend 9 to 10 visits to the center, including sessions of training and assessments of one-to-three-hours duration.
5. Able to read, understand, and provide informed consent.
6. Living in the US and speaks English or has a translator.

EXCLUSION CRITERIA

1. Diagnosis of neurological injury other than SCI;
2. Progressive condition that would be expected to result in changing neurological status;
3. Severe concurrent medical disease, illness or condition judged to be contraindicated by the site physician;
4. Unhealed or unstable traumatic or high impact lower extremity fracture of any duration that is, in the clinical judgement of the study physician, exclusionary for standing and walking;

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5. Knee (proximal tibia and/or distal femur) BMD <0.60 gm/cm²;
6. Total hip BMD T-scores < -3.5;
7. Fragility, minimal trauma, or low impact fracture of the lower extremity since SCI;
8. Untreatable severe spasticity judged to be contraindicated by the site physician;
9. Untreated/uncontrolled hypertension, as judged to be contraindicated by the site physician;
10. Unresolved orthostatic hypotension (change from baseline seated BP to a fall in 20mmHg SBP and/or fall in 10mmHG DBP and symptoms when standing), or as judged to be contraindicated by the site physician;
11. Open or unhealed skin pressure sores, abrasions, or bruises at any of the contact points of the exoskeleton;
12. Morphological contraindications to the use of the device;
13. Uncorrectable leg length discrepancy over 2 cm (about 0.79 in) when using additional correction tools;
14. Unable to effectively operate the device with a hand-control interface, due to functional and/or cognitive impairment, evaluated based on the ability to manipulate the joystick in all directions, press and identify buttons on the hand control interface.
15. Improper fitting in the device;
16. Psychopathology documentation in the medical record that may conflict with study objectives;
17. Pregnancy or women who plan to become pregnant during the study period;
18. Concurrent participation in another interventional trial.
19. History of uncontrolled autonomic dysreflexia;
20. Presence colostomy and/or urostomy;
21. Ventilator use at the time of the exoskeleton use.

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn that the Eve robotic walking device is safe and can be properly used by people with spinal cord injury (SCI), with a companion, to help them. The device, developed by Wandercraft, is a new type of robotic exoskeleton device, offering powered support to stand and walk again, without needing crutches or a walker. It can be used by people with higher-level SCI, who have limited hand function, thanks to a specially designed remote and trunk support. The Eve device is a new version of Wandercraft's Atalante X exoskeleton, already available in the US for rehabilitation, and with the data collected in this study, it will serve as a basis to seek approval for the sale of the Eve device in the US.

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HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 1 year. The study includes up to 10 visits that can last 1-3 hours.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

The enrollment goal of the study is to complete at least 24 pairs (SCI users and their companions). These pairs will be enrolled at either of the two study sites: 1) James J. Peters VA Medical Center, Bronx, New York or 2) Kessler Research Foundation, West Orange, New Jersey. You (SCI user) will be paired with your companion for the duration of the study. For participants enrolled at JJPVAMC, all study procedures will be done at the Spinal Cord Damage Research Center, James J. Peters VA Medical Center, Bronx, New York.

Visits

Your (users and companions) participation will consist of 10 visits. These visits will be as follows:

- **Visit 1: Screening visit.** If you have met all eligibility criteria and successfully completed all screening procedures you will be enrolled and proceed to visit 2. An additional Screening visit will be added if need be due to participant schedules. **In this case, the total number of visits is 10.** Screening procedures include an x-ray of both feet, Dual X-ray Absorptiometry (DXA) scans of both hips and knees, and a pregnancy test (if applicable). The International Standards Exam for Neurological Classification of Spinal Cord Injury (ISNCSCI) exam will be complete to determine your level of injury.
- **Visit 2 - Visit 6: Training sessions of 1 to 2 hours each.** A “device specialist trainer” from the investigation site will be responsible for training you and your companion to operate the device. The study team will have been trained and certified by Wandercraft to serve as trainers.
- The goal of the training is to ensure that you and your companion become proficient with the device “basic skills”, which include all the device critical tasks (critical tasks as defined by the FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices). **The basic skills are listed below:**
 - Setting up/down the device, transfer in/out, appropriate donning/doffing and device points of contact fitting.

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- Ambulatory functions: standing up/sitting down, standing balance with weight shifting, stepping up to 5 continuous steps, walking on indoor and outdoor surfaces, walking/stop/walking, turning right/left/180°, backward and lateral steps, leaning sideways and forward (weight transfer) and bending down (semi-squat).
- Activities of Daily Living (ADLs) such as, but not limited to, countertop work, above head cabinets, reaching up/down and carrying an object, housework, etc.
- Door navigation: elevators, automatic (revolving doors excluded) and manual doors.
- Safety procedures: handling loss of balance, fall safe mechanism and emergency extraction of the device.
- Proper care and device storage (e.g., power, battery charging, cleaning...).
- **Visit 6:** the final training session with the device, is concluded with a certification evaluation to ensure that you and your companion have mastered the required tasks to earn the 'Basic Skills' certificate. To accurately reflect the training process that actual users undergo, both in content and delivery method, the evaluation will not occur immediately post-training. A minimum delay of one hour will be instituted to allow for a natural decline in training retention, thus providing a more realistic assessment of skills mastery.

If you fail on one or several of the skills during visits 1 to 6, you are given a second chance to execute them correctly at the remaining visits (i.e., at Visits 7, 8 or 9).

You and your companion will be provided with written instructions for use of the device to take home, allowing them the flexibility to review the material at their convenience and to ask additional questions during the sessions.

- **Visit 7: Assessments with the Eve exoskeleton** (TUG, 6MWT, ADLs, 10MWT and don/doff) to support the primary and secondary objectives.
- **Visit 8: Additional practice session**, to allow you to progress on achieving the different basic skills.
- **Visit 9: Assessments with the Eve exoskeleton** (same as Visit 7) will be administered a second time. These tests will be followed by a modified Gagnon questionnaire. You will be asked to report perceived clinical changes in control of the sitting balance, general endurance during daily activities, leg spasticity, intestinal elimination, sleep quality, mental health and psychological well-being and general state of health.

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Environment

During the sessions with the exoskeleton, the participants will engage in mobility activities on different surfaces and perform ADLs in simulated environments, including:

- Kitchen with standard-height counters, cupboards, to simulate using common appliances.
- Rooms with furniture to simulate walking around, sitting and standing from chairs, retrieving objects, and navigating to the next room.
- Bathroom to simulate using facilities such as reaching a sink for self-care activities.
- Hallway and Entryway, to simulate navigating through doorways.
- Elevators to simulate transitions between different floors (including automatic doors)

Outdoor spaces to simulate walking on irregular surfaces, including grass, asphalt/cement.

Measures will be taken at each exoskeleton session

- Monitoring of vital signs (manual BPM and HR) before, during and after each session with a cuff, and during the session using smart monitor (i.e., with apple watch or other devices).
- Number of steps, distance covered and upright time.
- Number of times the users ambulate on each type of surface.

<i>Test/Measure</i>	<i>Screening and enrollment</i>	<i>Training sessions</i>					<i>Assessments</i>	<i>Additional practice session</i>	<i>Assessments</i>
	<i>Visit 1</i>	<i>Visit 2</i>	<i>Visit 3</i>	<i>Visit 4</i>	<i>Visit 5</i>	<i>Visit 6</i>	<i>Visit 7</i>	<i>Visit 8</i>	<i>Visit 9</i>
<i>BMD</i>	x								
<i>ASIA score</i>	x								
<i>Bi-lateral foot X-rays</i>	x								
<i>Measurements and fitting screening (SCI user)</i>	x								
<i>Physical ability screening (companion)</i>	x								
<i>PHI data</i>	x								

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Safety

AE collection	x	x	x	x	x	x	x	x	x
HR and BPM before, during and after session	x	x	x	x	x	x	x	x	x
Skin inspection prior/after device use	x	x	x	x	x	x	x	x	x

Primary effectiveness outcome measures

TUG							x		x
6MWT							x		x

Secondary outcome measures

ADLs							x		x
10MWT							x		x
Don/doff time							x		x

Exploratory outcome measures

# steps, distance and up-right time, # of times the participants walk on each type of surface		x	x	x	x	x	x	x	x
Level of companion assistance		x when mastering each basic skill - on the checklist - at initial learning and at visit 6 for the critical tasks					x for each test	x for each basic skill on the checklist	x for each test
Perceived exertion (RPE)						x	x		x
Perceived safety						x	x		x
Gagnon questionnaire									x

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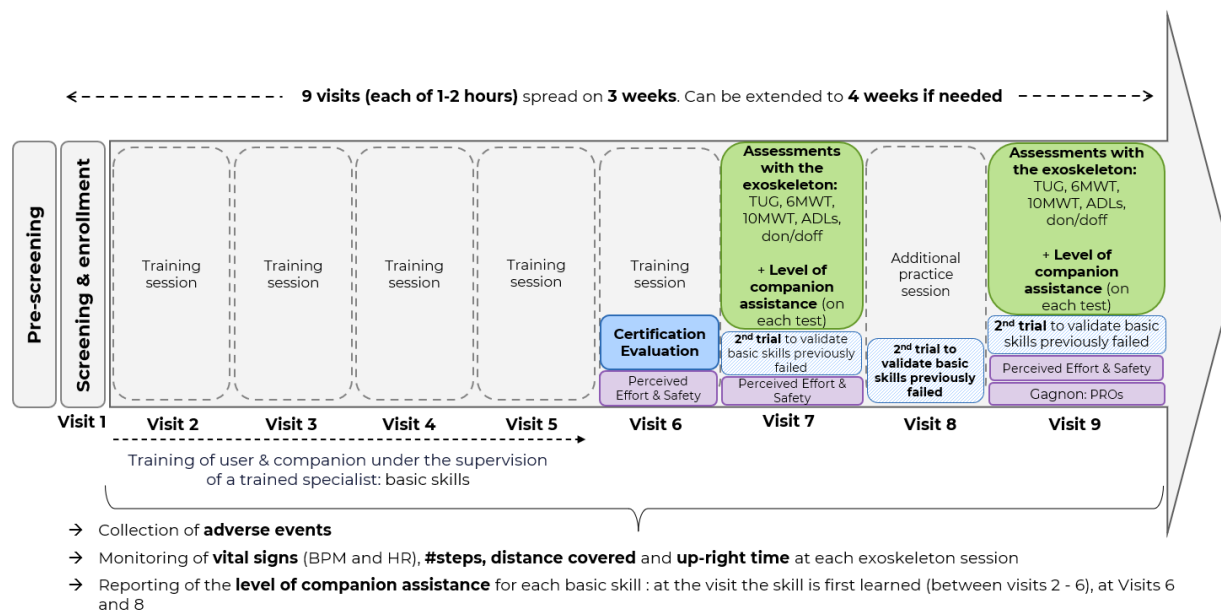


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The sponsor is requesting to take video footage of you while you are walking in the device in order to improve future generations of this device. Your face will be blurred with special software on the camera and you will not be identifiable to protect your privacy. Do you consent for video's to be taken of you while you are using the device?

☐

By checking and initialing this box, you agree have video recorded of you walking in the device.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Use the study device as instructed.
- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant or might have gotten your partner pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.

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- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

During the study, you are at risk of:

- muscle and joint aches;
- blood pressure changes;
- skin abrasions;
- swelling or bruising due to rubbing at the contact points of the device;
- broken bones, bruising, or swelling of the feet; and
- falling is possible during training with the device. With a fall, you are at additional risk of:
 - muscle and joint sprain;
 - bruising;
 - broken bones; or
 - other unknown injuries.

DXA Scan: The DXA scan carry a small risk associated with low levels of radiation used in the scan. The DXA measurements combined will be approximately 50% of the radiation received from a routine chest x-ray. The DXA measurements in total will be ~0.03 to 0.05 mSv of radiation exposure, which equates to ~4 to 6 times the amount of daily natural background radiation (approximately 0.008 mSv).

X-ray of Feet: The X-ray of each foot does carry a small risk associated with low levels of radiation used in the scans. You will be exposed to approximately 0.03 mSv of radiation.

During the sit-to-stand and stand-to-sit, 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

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aware and the test will be stopped immediately. During this portion of the study you may also experience muscle and joint aches, joint sprain, muscle strain, 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. The largest possible risk associated with testing these devices is falling. The potential of this occurring will be minimized by having study staff highly experienced in gait training be present during all exoskeletal training. While the risk of a broken bone is small, it is important to understand that it is possible during this portion of this study. Other possible risks include discomfort, triggered spasm, reflex bowel or bladder activity, skin pressure/ friction or autonomic instability during use of the device. Last, 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 staff from the VA Bronx, who have been conducting exoskeletal-assisted locomotion studies for 10+ years.
2. To minimize the risk of falling:
 - a. Overground movement experiments: To minimize the risk of slipping and tripping over any obstacles, the areas used for the sit-to-stand, stand-to-sit, walking, and stepping will be checked before and during each session to be free of any obstacles. A safety harness on a moving gantry system is available. If you require the safety harness, the research team will outfit you with the safety harness and secure to the gantry system prior to the experiments.
 - b. The handles of the exoskeleton device will be used by the study staff to provide stabilizing assistance during exoskeletal-assisted locomotion, as appropriate.
 - c. you will be flanked by two study team members, one on each side during all WALK sessions. Study team members will always be by your side while you use the exoskeleton device to provide physical support, if needed.
 - d. You will never be left unattended when using the exoskeleton device.
3. To minimize the risk of a broken bone, measurement of the bone mineral density will be obtained as part of the screening for participation in this study. If your bone mass is too low, you will be excluded from the study. In addition, you will be checked after each locomotion task for signs of swelling. If present, the experiment will be discontinued, and then you will be instructed to consult with your primary care physician.
4. The power source of the system will be supplied with a fully charged battery and a back-up battery.
5. After fitted in an exoskeleton, you will be examined at contact points for skin redness, irritation, or breakdown before and after each locomotion task. If evidence of skin redness, irritation or breakdown exists, alternate placements for straps and/or padding will be used to protect the area.

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6. Upon completion of the study, you will not have access to this device. If you develop feelings of sadness or becomes depressed after completion of the experiments, you will be instructed to consult with your primary care physician.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this research consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may be no direct benefits to you from this study, but any information that the researchers get from this study may help others. If an abnormality that may be clinically treated is identified during the study, it will be brought to you and/or your physician's attention.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Participation in the study is voluntary and the alternative to this study is to not participate and seek clinical advice from your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your research records will be maintained according to the requirements of the JJPVAMC as follows:

Data Collection, Storage, and Transfer:

- Your coded electronic data will be collected on Non-VA computers that are not connected to the internet.*
- Your coded electronic data without your name, or other identifying information, will be stored on secured networks, behind electronic security systems, in access-restricted folders.*
- Hard copies of your data will be stored in a locked file cabinet behind 2 locked doors.*
- Electronic Data Repository: behind VA firewall.*

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Access to the research materials generated from the study will be restricted to Dr. Spungen's research team. 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. In order to comply with federal regulations, research records identifying me may be reviewed by the following:

The study sponsor [Wandercraft SAS] of this study, authorized representatives of the JJPVAMC (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).

We will include information about your study participation in your medical record.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

As a veteran or non-veteran, you or your insurance 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 understand that you will receive \$25 for your participation in each visit. Payment will be in the form of an electronic fund transfer (EFT) sent directly to your bank, check, or pre-paid card. You may be required to provide the research staff with information that includes the name of your bank, routing number and account number to complete the EFT. Reimbursement typically takes 6-8 weeks after completing the visit due to the administrative processing time.

Payment Schedule:

Visit 1(Screening: DXA, X-Ray): \$25

Visits 2-9 (Exoskeleton Visits): \$25 each visit

Visit 10 (End of Study Evaluation): \$25

Total: up to \$250

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Reimbursement for Transportation:

Participants with SCI who must travel to the study site will be reimbursed for transportation and accommodation costs, upon presentation of receipts. Individuals with SCI who are screened but not enrolled will be reimbursed for up to \$800. Enrolled participants who have passed screening will be reimbursed for up to \$1500 at the end of their participation, reflecting longer stay and lodging expenses.

If you opt to be reimbursed by a pre-paid card or direct deposit, we will process that through the company Greenphire. Greenphire is a company working on behalf of The Bronx Veterans Medical Research Foundation (BVMRF) to support this reimbursement process. In order for you to get paid, Greenphire will need to process certain personal information about you. This information will be collected from you by the study staff study and given to Greenphire.

Greenphire will collect and use your information for the following purpose(s): ClinCard. You may be issued a Greenphire ClinCard, which is a debit card that your funds are loaded onto. When a study visit is completed, funds will be approved and loaded onto your ClinCard. The funds will be available within 1 business day and can be used to pay for anything you need. To assign a ClinCard to you and load funds onto the ClinCard, Greenphire will need your Name, Address, and Date of Birth.

Taxation: Payment received as compensation for participation in research is considered taxable income. If payment exceeds \$600 in any one calendar year, Greenphire will file a 1099 (Miscellaneous Income) form on behalf of BVMRF. Greenphire will need your Name, Address, and Social Security Number.

Greenphire has administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of your personal information. Your personal information will be used and disclosed only to support the described research activities, including to service providers who assist us in managing, administering, or delivering the Services. Your personal information will not be shared by Greenphire or sold, used, or distributed for any other purpose. Your information will be kept for as long as necessary to provide the described activities and for compliance with applicable laws. You can exercise your rights to access, correct, modify, or delete your information at any time by contacting the staff from this study. If you exercise your rights or take away your consent, the study staff will not further transfer your personal information to Greenphire; however, this may not affect processing that occurred before you took away consent.

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WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

If you are injured as a result of taking part in this study, you will not receive additional compensation. You will not give up any legal rights or release the VA from any liability by signing this form.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Dr. Stephen Kornfeld at 718-584-9000 ext. 5424

and

AFTER HOURS:

Dr. Stephen Kornfeld at 718-668-4945

DO I HAVE TO TAKE PART IN THE STUDY?

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.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

You can refuse to participate now, or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment if you are a patient. The investigator also has the right to withdraw you from the study at any time for reasons including, but not limited to, medical concerns (your health and safety are in jeopardy with continued participation in the study), noncompliance (you miss several scheduled appointments without notification) and protocol deviations (exclusion/inclusion criteria change and you are no longer eligible to participate).

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WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions about your rights as a research subject concerns and/or complaints or to offer input and would like to speak to someone outside of the research team, you may contact the Associate Chief of Staff for Research (ACOS/R) Office at (718) 741-4228 or the hospital extension 4228 first floor in the research building, room 1F-01 to request an appointment with the ACOS/R or designee.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms./Mrs. _____

has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this form.

_____	_____	_____
Participant's Name	Participant's Signature	Date

FOR IRB USE ONLY

PI/SC Approval Date:



Participant Name:

Date:

Title of Study: Empowering mobility in people with Spinal Cord Injury with a hands-free, self-balancing personal exoskeleton

Principal Investigator: Ann M. Spungen, EdD VA Facility: James J Peters VA Medical Center

VERBAL CONSENT IF THE PARTICIPANT LACKS UPPER LIMB FUNCTIONS TO COMFORTABLY WRITE

_____ is unable to sign the consent form due to impaired arm function. I certify that I have carefully explained the purpose and nature of this research to him/her in appropriate language and he/she has had an opportunity to discuss it with me in detail. I have answered all of his/her questions and he/she has consented to participate in this research. I, therefore, am signing the consent form to document that he/she has given his/her consent to participate in this research study.

Person Obtaining Consent:

Name: _____

Signature: _____

Date: _____

Witness Name: _____

Signature: _____

Date: _____

FOR IRB USE ONLY

PI/SC Approval Date: