Informed Consent Form

Mobility and Therapeutic Benefits resulting from Exoskeleton Use in a Clinical Setting (SC140121 Study 1)

NCT03082898

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Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Michael Goldfarb, PhD **Revision Date: February 4, 2016**
Study Title: Mobility and Therapeutic Benefits Resulting from Exoskeleton use in a Clinical Setting (SC140121 Study 1)
Institution/Hospital: Vanderbilt University

This informed consent applies to Adults

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

The purpose of this specific study is to assess whether or not consistent walking in an exoskeletal device provides health benefits, and to assess the level of mobility provided by the exoskeletal device. The exoskeletal device (or exoskeleton) used in this study is the Indego Exoskeleton, which is a powered orthosis with electric motors at the hip and knee joints. It is not intended to replace a wheelchair as a primary means of mobility, but rather is intended to provide the physiological and psychological benefits associated with weight-bearing movement. It is also intended to enable legged locomotion in environments not well-suited to a wheelchair.

Funding for this research study is provided by Congressionally Directed Medical Research Program (CDMRP). We enroll a total of 24 participants at 3 sites. These sites include Vanderbilt, Tampa Veteran's Administration and Mayo Clinic. We plan to enroll about 8 participants at Vanderbilt.

2. What will happen and how long will you be in the study?

Each individual will walk in the Exoskeleton for approximately one hour per session, three sessions per week, for a period of eight weeks. Several different non-invasive measurements will be taken at the start of the study, at the end, and at various mid-points, in order to track changes in health. This study will require a commitment of approximately 30 sessions over the course of approximately 11 weeks, with one additional follow-up session approximately 18 weeks after the first session.

Study Days:

The study sessions will be structured as described below:

- Session 1: Informed consent and pre-treatment health assessment, including Dexa Scan (x-ray picture of the bone) of the distal femur and proximal tibia locations and we will draw about 2 teaspoons (9.5 mL) of blood to check your A1C (measures the amount of hemoglobin in the blood that has glucose attached to it) and Lipid Panel to measure cholesterol levels (lasting 4 hours).

- Sessions 2-4: Exoskeleton fitting, adjustment, and training sessions (3 sessions per week lasting 1.5 hours per session).

- Sessions 5-16: Exoskeleton walking during 1.5-hr sessions, with breaks as needed (3 sessions per week lasting 1.5 hours). Sessions 15 and 16 additionally involve timed walking tests in the exoskeleton.

- Session 17: Mid-treatment assessment session (lasting 3-4 hours).

- Sessions 18-29: Exoskeleton walking during 1.5-hour sessions, with breaks as needed (3 sessions per week lasting 1.5 hours per session). Sessions 28 and 29 additionally involve timed walking tests in the exoskeleton.

- Session 30: Post-treatment health assessment, within 3 days of session 29 including Dexa Scan (x-ray picture of the bone) of the distal femur and proximal tibia locations, and 2 teaspoons (9.5 mL) of blood to check your A1C (measures the amount of hemoglobin in the blood that has glucose attached to it) and Lipid Panel to measure cholesterol levels (lasting 3-4 hours).

- Session 31: Follow-up health assessment, including Dexa Scan (x-ray picture of the bone) of the distal femur and proximal tibia locations and 2 teaspoons (9.5 mL) of blood to check your A1C (measures the amount of hemoglobin in the blood that has glucose attached to it) and Lipid Panel to measure cholesterol levels, 8 weeks following session 30 (lasting 3-4 hours).

Women of child bearing potential will have a urine pregnancy test at baseline and sessions 17, 30 and 31.

You will be required to wear a safety gait belt during all upright activity, which is intended to reduce your risk for a fall. For your safety, before and after each session, the physical therapist will take your blood pressure and heart rate, and inspect your skin where it comes in contact with the device.

Although the intent of enrollment is for you to participate in all 31 sessions, you may discontinue your participation in this study at any time.

Photographs and Videotape: The research team will take photographs and record videos of you throughout this study. Your entire body including your face will be included. The purpose of the photographs and video is to help you learn more about the device as well as to provide information to the researchers and for other participants in this or other studies. The photographs and videotapes may also be used for scientific publications, meetings of scientists, public formats for nonscientific groups.

☐ I give my permission for the use any photographs or videos taken of myself during this research project. I may at any time withdraw permission for photographs or videos of me to be used in this research study.

☐ I do not give my permission for the use any photographs or videos taken of myself during this research study to be used outside this study.

3. Costs to you if you take part in this study:

There is no cost to you for taking part in this study. You must arrange for your own housing and transportation while taking part in this study.

4. Side effects and risks that you can expect if you take part in this study:

The risks to you are similar to those that may happen while learning to walk with other walking aids, such as a leg braces, after a spinal cord injury. Risks include muscle soreness, fatigue, skin irritation, fracture, changes in blood pressure, and potential for a fall. Systems that researchers have in place to reduce any side effects and risks to you include: allowing you frequent rest breaks, taking your vital signs before, during and after each session, monitoring your skin, and using a safety gait belt. Additionally, a physical therapist will directly oversee all walking sessions.

5. Risks that are not known:

Because this device is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.
There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study. This study is expected to provide the medical community a better understanding of the effects of exoskeletal walking.
b) The benefits you might get from being in this study. You may or may not receive benefit from this study.

8. Other treatments you could get if you decide not to be in this study:

There are no other treatments related to whether or not you participate in this study.

9. Payments for your time spent taking part in this study or expenses:

You will be paid $25 per visit for your involvement for up to $775. In addition to receiving mileage and parking reimbursement for travel to and from the trial site.

This amount may be taxable and will be reported to the Internal Revenue Service (IRS).This money is meant to assist you in paying any travel expenses, lost wages from work, child care, etc. that you may have as a result of taking part in this study.

If you discontinue early from the study, you will receive a pro-rated reimbursement amount based on completed study visits.

We will ask you for your Social Security number and address before you are compensated for taking part in this study.

10. Reasons why the study doctor may take you out of this study:

You will be removed from the study if there is any concern for your safety by a member of the research team. If you are removed from the study, you will be told the reason

11. What will happen if you decide to stop being in this study?

You can decide to stop being in this study at any time. Your care at this facility that is unrelated to this study will NOT be affected if you decide to stop being in this study. If you decide to stop being part of the study, please let a member of the research team know as soon as possible. You should also let your doctor know that you decided to stop being in the Exoskeleton study.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Michael Goldfarb, Vanderbilt University Center for Intelligent Mechatronics at (615) 343-6924 or at michael.goldfarb@vanderbilt.edu .

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Clinical Trials Registry.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

14. Confidentiality:

All data, videos, and photographs recorded during this study will be held in a secured location at the trial site. Data will continue to be held until the study researchers deem the data is no longer scientifically relevant, at which point the data will be destroyed.

All efforts, within reason, will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

A unique study identification (ID) number will be assigned to you and will be used on all study data records. The file that links your personally identifiable information with the unique study ID number assigned to you will be kept in a secure file only accessible to the research staff. Your name and any other identifying information collected will be kept in a secure location only accessible to research staff. These precautions are expected to be completely effective in eliminating risks to confidentiality.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Michael Goldfarb and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information. Records of your participation in this study will be held confidential except as disclosure if required by law or as described in this informed consent document (under “Confidentiality”).

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr Goldfarb and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing (“disclosure”) such data must follow federal privacy rules. By signing the consent for this study, you are agreeing (“authorization”) to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Goldfarb and his study team may share the results of your study and/or non-study linked Medical and research records identifying you and describing your medical condition, records about your study visits, records of physical exams, laboratory, x-ray, and other test results, photographs, videos, questionnaires, records about medications, as well as parts of your medical record, to the groups named below. These groups may include people from the Tampa Veteran’s Administration, Mayo Clinic,

Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, The U.S. Food and Drug Administration (FDA) Department of Health and Human Services (DHHS) agencies, Other U.S. and foreign governmental agencies, Institutional Review Boards and/or Research Review Committee. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.
Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Goldfarb in writing and let him know that you withdraw your consent. His mailing address *is Mechanical Engineering Department 2400 Highland Avenue 336C Olin Hall Nashville, TN, 37212.* At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY
I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title