1414 Harbour Way South
Suite 1201
Richmond, CA 94804
Office: 510-984-1761
Fax: 510-927-2648
customerrelations@eksobionics.com

# EKSO BIONICS SPOTTER CONSENT FORM FOR RESEARCH

**Investigational Study of the Ekso Bionics Powered Exoskeleton for High-Dosage Use by Individuals with Spinal Cord Injury Walking in a Non-Clinical Environment**

**PRINCIPAL INVESTIGATOR: Katherine Strausser, PhD, Sr. Controls Engineer**

## Introduction

You are being asked to take part in a research study because you have agreed to be a spotter to a spinal cord injury participant that has an impaired ability to walk. If you are eligible and agree to participate, you will be asked to use a device that helps the participant walk in their home for up to 3 years.

Your participation in this study is entirely voluntary. This document has important information about the reason for the study, what you will do if you choose to be in this research study and the way Ekso Bionics would like to use information about you and your assistance. You should read the information below and ask questions regarding anything you do not understand prior to deciding whether or not you choose to participate in this study.

## What is the reason for doing this study?

We are looking for up to 12 people with spinal cord injury to participate in this study. This study will require that each participant use a device that consists of a brace (exoskeleton) that extends from the trunk (torso) to the feet. It has battery-powered motorized hinges that produce joint motion at the hips and knees, and is capable of producing powered brace-walking. You will be asked to be a spotter to the participant walking in this device for at least 60 minutes per day for 4 to 6 days per week in their home for up to 3 years.

The purpose of this study is to:

1) determine the effects of walking in the device on body functions such as pain, spasticity, and bowel/bladder function
2) document your perception of your quality of life as a result of spotting the participant walking in the device
3) determine the safety of using the device in a home being a spotter who is not a licensed medical professional (for example a physical therapist)
4) determine the criteria for use of this device in a home setting

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**What you will do if you choose to be in this study?**

If you agree to be a spotter, you will be asked to complete Spotter Training. You will be trained by a physical therapist on how to operate the device and safely spot the participant for safety for all walking that they perform in their home. Spotter Training will be either at Ekso Bionics, 1414 Harbour Way South, Suite 1201, Richmond, CA 94804, or in the participant's home. Training consists of the following:

- 3 days of training with a review at the end of each day
- 6 sessions per day lasting approximately 2 hours each
- Initial device training procedures include:
    - Putting on the device on the participant with the assistance of the Ekso Bionics staff. You will be instructed on how to perform the intended task(s) in preparation for device use in your home. Tasks may include:
        - Informing of device functions, failure modes and common characteristics.
        - Safety and how to respond to various conditions including being off balance, uneven ground.
        - Device set-up and take-down
        - Operating the device.
        - Putting the device on and taking the device off.
        - Sitting/Standing
        - Walking
        - Supporting the subject
        - Helping the subject safely perform simple daily tasks inaccessible to the subject while in the device (e.g., bend down to get a plate from a cabinet or open a door)
    - Assisting the participant with removing the device as needed.

**Spotter Inclusion Criteria – you are eligible to participate in the study if all of the following apply:**

- Are between 18-65 years of age.
- Physically fit
- Able to lift and carry the Ekso device (50 pounds).
- Able to support the subject if off balance.
- Able to guide the subject to a safe position in case of a fall.
- Are certified in First Aid
- Are available at least four days per week for at least five out of every six weeks throughout the duration of the study. If more than one spotter will be working with the participant, then spotters together must meet these criteria.
- Are fluent in speaking and reading English
- Are able to read the LCD display
- Are able to hear device alarms and tones

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**Spotter Exclusion Criteria – you are not eligible to participate in the study if either of the following applies:**

- Known muscular-skeletal or other medical condition that could cause regular delays of the study if spotter is injured or impaired.
- Pregnancy (Self-Reported)

**Following your Spotter Training, you will be asked to:**

Complete an Ekso Non-Clinical Spotter Questionnaire

Participate in the following prior to starting the home walking program, and again after 3 months, 6, months, 9 months, and 1 year of the participants use and every 6 months thereafter (each assessment will be +/- 2 weeks of given time interval):

- Evaluations on your opinion about how hard you a working while spotting the participant
- Evaluations on your comfort level while spotting the participant
- Provide any feedback you may have

Spot the participant while they walk in the device while in their home.

- You will be asked to spot the participant while they walk in the device 4 to 6 days per week.
- You will be asked to spot the participant while they walk in the device for a minimum of 60 minutes a day and no more than 6 hours a day.

**What are some of the risks and discomforts that may happen? Your participation in this study may involve the following risks:**

1) The risk of falling or being pulled down: This could happen if you or the participant loses control of the walking activity. It may also happen if there is a malfunction of the Ekso device itself. Having experienced spotters conduct the training sessions with manual assistance and overhead attachment to the tethered support system will minimize the risk of falling.

2) Discomfort, soreness, bruising, or pain caused by fatigue of spotting the participant. This risk will be minimized with spotting experience.

3) The device itself could malfunction. In the event of device malfunction, the device will lock and you need to assist the participant out of the device.

The use of the Ekso system may involve risks that are currently unforeseeable as this is a trial to assess safety and efficacy of the Ekso device. Due to the above stated risks, you cannot participate in the study if you are pregnant.

**What are some of the benefits that are likely to come from your being in this study?**
There may be no direct benefit to you by your participation in this research study. However, your participation may help the investigators to improve the design of the device and in training methods.

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Your participation in this study is voluntary and you are free to withdraw at any time. Any new findings developed during the course of this research that may affect your willingness to continue will be provided to you.

**Are there any financial costs to being in this study?**

- Training costs – Ekso Bionics will be responsible for all training costs related to training you as the spotters.
- Spotter costs – You must be first-aid certified prior to training. Certification is at the participant's expense.

**Who can you call if you have questions or concerns about this research study?**
You can ask the person discussing this consent form with you if you have any questions. You can also call us, Ekso Bionics, with your questions or concerns. If you are injured during your time on this study, you should call us promptly.

Contact person for question or if injured:

Katherine Strausser, PhD
Sr. Controls Engineer
Principal Study Investigator
Ekso Bionics, Inc.
Main: 510-984-1761
Direct: 510-529-2529
Monday 9 AM to Friday 5 PM, Pacific Time

If you have concerns you do not want to discuss with Ekso Bionics or if you have questions about your rights, or to offer input you can contact Ethical & Independent Review Services (E&I) at 800-472-3241 or by email at subject@eandireview.com.

**What are my rights as a research subject?**
If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time.

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 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.

## MANDATORY REPORTING REGARDING ELDER/DISABLED

Ekso Bionics is a mandatory reporter under the Elder Abuse and Dependent Adult Civil Protection Act. Under California law, Ekso Bionics will not maintain as confidential, information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder, including, but not limited to, physical, sexual, emotional, and financial abuse or neglect. If any Ekso Bionics employee has or is given such information, he or she may be required to report it to the authorities.

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**Optional Elements [Choose One]:**

_____(Initial) I give permission for photographs or videotapes of me that DO include my face to be used in scientific publications, presentations, marketing or publicity materials.

_____(Initial) I give permission for photographs or videotapes of me that DO NOT include my face to be used in scientific publications, presentations, marketing or publicity materials.

_____(Initial) I DO NOT give permission for photographs or videotapes of me to be used in scientific publications, presentations, marketing or publicity materials.

**Consent Summary:**
I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above.

This consent form will be provided to me after I sign it.

_____

**Subject's Name (printed)** **(signature)** **Date**

_____

**Name of Person Obtaining Consent (printed)** **(signature)** **Date**

_____

**Principal Investigator (printed)** **(signature)** **Date**