Informed Consent Form Companion

Official Study Title: Empowering mobility in people with Spinal Cord Injury with a hands free self-balancing personal exoskeleton (site 2)

NCT number: NCT06814015

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KESSLER FOUNDATION

INSTITUTIONAL REVIEW BOARD

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY: Empowering mobility in people with Spinal Cord Injury with a hands-free, self-balancing personal exoskeleton

RESEARCH STUDY #: R-1272-24

Companion Consent

I, _____, am being asked to consent to participate in a research study led by Dr(s). Gail F. Forrest, Ann Spungen and Saikat Pal. Other persons who work with them as study staff may be asked to help them. I understand that taking part in this study is completely voluntary; I do not have to be part of this study unless I choose to be. I am free to leave the study at any time if I change my mind. All research studies carried out at Kessler Foundation are covered by the rules of both the Federal Government and Kessler Foundation.

The information provided may contain words I do not understand. I will ask the study doctor or the study staff to explain any words or procedures I do not understand.

The table below contains a brief summary of key information about this research study. Additional information can be found throughout this document.

Study Summary	
Why is this research being done?	The aim of this study is to determine if a wearable robot (referred to as an exoskeleton) can improve the ability to walk over ground and perform activities in standing for individuals who have a spinal cord injury. The exoskeleton device that will be evaluated is named the “Eve” (manufactured by Wandercraft).
How long does the study last?	The study will take me 2-4 weeks to complete. This includes up to 10 visits that can last 1-2 hours each.
What will happen during this research study?	While I am part of this study, I will be asked to participate in the following: ▪ Training on the device use and assisting ▪ Assisting with walking tests in the exoskeleton ▪ Giving feedback on the training sessions I will receive an invitation to participate in an optional follow-up activity when I have completed my study visits. It takes an hour to complete and consists of watching a presentation and answering questions about it.

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What risks are associated with participating in this study?	Injuries, such as bruising or discomfort, may occur if the device user falls as a result of my assisting with the device.
What are the benefits of participating in this research study?	I will receive no direct benefit from taking part in this study, but the information obtained from this study may help the researchers to better understand the usefulness of new technology to enhance walking for people with spinal cord injury.
What other options are available to me if I choose not to participate in this study?	Participation in this study is completely voluntary. If I choose not to participate in this study, there will be no effect on my medical care, employment status, or access to benefits to which I am otherwise entitled.

The following sections offer more detail about the study.

WHY IS THIS RESEARCH BEING DONE?

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. The device is approximately 132lbs and the size of the device is customized to the user's body measurements, but can reach a maximum height of 6 feet 7 inches. It can be used by people with higher-level SCI, who have limited hand function, thanks to a specially designed remote and trunk (torso) support. The Eve device is a new version of Wandercraft's Atalante X exoskeleton, already available in the US for rehabilitation. This device comes with a system of safety features that protects the head, neck, and upper body in the event of a fall. The data collected in this study will serve as a basis to seek approval for the sale of the Eve device in the US. The Eve device is considered an investigational device for purposes of this study because it is not yet approved for sale.





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WHAT WILL HAPPEN DURING THIS RESEARCH STUDY?

While I am a part of this study, I will be asked to do the following:

- Use the study device as instructed.
- Keep my study appointments. If I miss an appointment, I will contact the investigator or research staff to reschedule as soon as I know I will miss the appointment.
- Tell the investigator or research staff if I believe I might be pregnant (because of potential injury to the fetus).
- Complete my questionnaires as instructed.
- Ask questions as I think of them.
- While participating in this research study, I will not take part in any other research project without approval from the investigators.

Visits:

My participation will consist of up to 10 visits at Kessler Foundation. These visits will be spread over a 2-4 week period depending upon my availability. (If I live too far to commute daily to Kessler Foundation, these visits will be scheduled closer together so that the amount of time I need to stay nearby is reduced.) Every session the device is used, study staff will monitor the device user's vital signs before, during, and after the visit. These visits will be as follows:

Visit 1 – Screening and enrollment visit (2nd visit for screening may be added if needed)
Visit 2 to Visit 6 - Training sessions of 1 to 2 hours each
Visit 7 – Performance Test
Training retention day (no visit to the study site this day)
Visit 8 – Additional practice session
Visit 9 – Performance test

Visit 1: Screening visit.

I will be tested on my ability to keep the exoskeleton balanced and accompany the device to the ground in case of a fall.

I will take a pregnancy test (if applicable).

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March 11, 2027

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If the device user has met all eligibility criteria and successfully completed all screening procedures, we will proceed to visit 2. An additional Screening visit will be added if needed.

Visit 2 - Visit 6: Training sessions of 1 to 2 hours each.

An experienced trainer will be responsible for training me and the device user to operate the device. The study team will have been trained and certified by Wandercraft to serve as trainers. I will be trained on how to assist the device user within the medical center. Depending on how much assistance the user of the device needs, I may be trained to physically assist them by providing contact to their hips, trunk (torso), or shoulders. I will learn these skills during the multiple 1-to-2-hour training sessions. I will learn the major components and basic functions which include the: battery, computer, controller, and frame. During this time, I will be taught how to assist the user with putting on and taking off the device and to use the controller to perform the standing, sitting, and walking skills. I will also learn how to assist the user with walking over different surfaces, reaching, turning, and stopping skills while in the device. The user and I will be taught how to operate, charge, maintain and store the device. The goal of the training is to ensure that we become proficient with all the critical and essential tasks required for safe and effective device use in home and community-like environments set up at the study site. **These foundational tasks are referred to as "basic skills":**

- Setting up and taking down the device, transferring in and out, putting on and taking off and device points of contact fitting.
- Moving 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 side 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, refrigerator use, housework, etc. These will be chosen by me as the ones most relevant to my ADLs.
- Door navigation: elevators, automatic (revolving doors excluded) and manual doors.
- Safety procedures: handling loss of balance, safety mechanisms in case of a fall, and emergency exit of the device. This will include practicing safe lowering to the floor and getting out of the device from the floor.
- Proper care and device storage (e.g., power, battery charging, cleaning…).

These tasks will require me to provide physical assistance similar to that provided with transfers, dressing, and other similar tasks at home. In the event of a fall or balance event, I may need to support the full weight of the user in the device.



At the end of Visit 3 and Visit 6, the device user and I will be asked our opinions on the device from the session.

We will be provided with written instructions for use of the device, allowing flexibility to review the material at our convenience and to ask additional questions during the sessions.

Visit 7: Performance test with the Eve exoskeleton.

The study staff will explain the content and goal of this visit, which will include assessments based on the basic skills taught in the training sessions.

Training retention period of one day (or more). This is a one-day break from training. Having this break will help researchers assess how well I remember what was trained, even if some time has passed. This helps make the testing more realistic, as this break in training mirrors what future users will experience.

Visit 8: Additional practice session

Allows me to progress on achieving the different basic skills described above.

Visit 9: Performance test with the exoskeleton (same as Visit 7).

The performance tests will be followed by a questionnaire. It will include questions about my physical and mental experiences during the training period.

If I **fail on one or several of the critical tasks at my first attempt of the Performance Test,** I will be given a **second chance to perform the safe execution of these tasks** at the remaining visits (i.e., at Visits 7, 8, or 9).

During the sessions with the exoskeleton, I will perform moving activities on different surfaces (both indoor and outdoor, e.g., tile, carpet, cement, grass) and different settings (e.g., apartment, adapted or not) at the research center. A certified trainer will be present during all sessions to handle the training, make sure the test is performed correctly, evaluate the amount of assistance I need to provide, and provide additional support as needed. I will practice inspecting the device user's skin, under the trainer's supervision, to make sure there are no problems present that would prevent use of the exoskeleton.

I will be provided a certificate at the end of the study if I demonstrate appropriate performance of all required tasks.

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March 11, 2027
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Measures will be taken at each exoskeleton session.

- Monitoring of vital signs (manual blood pressure and heart rate) 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.

I will be audio and/or video recorded during the study, so that the researchers may collect all the information they need correctly. If I do not agree to be audio/video recorded, I will not be able to participate in this study.

I understand that in some Kessler Foundation testing rooms there are video cameras that operate for security purposes. The recordings of these cameras are not provided to the research staff.

In the event of equipment malfunction, as a companion, I will be able to assist the device user down to a flat surface and be able to direct an additional person to assist me, if necessary.
In case of a medical emergency, as a companion, I will call 911, or be able to get help for the device user including activating an emergency response, and direct someone else to assist me in doing so, if necessary.

If the user in the exoskeleton were to fall and the fall did not cause any harm to them, I will be expected to assist him or her out of the exoskeleton and back into their wheelchair as soon as feasible.

Optional Follow-Up Activity

Upon completion of the in-person study visits, I will receive an invitation to take part in a short follow-up activity. This **optional** activity takes about an hour to complete. Everything is done remotely, so no travel or in-person visits are required. Completing the activity will help researchers understand whether the device instructions are clear and meet the needs of its users.

If I agree to participate in the follow-up activity I will be asked to:

1. **Follow the instructions in the email** invite by signing the Informed Consent Form, to indicate my agreement to take part. After signing, I will receive a copy of my signed consent form. A member of the research team will then contact me with a proposed time slot for the video call within the next 10 days.

2. **Watch a narrated presentation (~27 min)** I will receive a link to watch the presentation via email. The video is refresher training on the use of the device, and covers specific changes on the remote control's lights, which have slightly updated since I participated in the study. I will be reminded to watch it carefully, since I will be asked questions based on its content. I can watch it at my own pace, pause, or rewatch it as needed.



Before the video call, I am encouraged to browse through the enclosed Information for Use (IFU) to familiarize myself with its structure and content. This will help me refer to it efficiently during the call, if needed.

3. **Complete a post-training questionnaire by video call (~30 min)** I will join a video call with a member of the study team. Before the questionnaire begins, I will have the opportunity to ask any questions I might have about training points that were unclear or anything else I wish to discuss. Then, questions will be asked and answered verbally (no written answers required). I am allowed to use the presentation and other reference sheets sent to me at any time during the call. The purpose of this activity is not to grade my personal performance, but to check whether the updated device information is clear and easy to understand. My responses will be recorded under my study ID only- No new sensitive information will be collected.

   The video call will be audio recorded to verify and accurately report data. Recordings will be stored securely on a password-protected, access-restricted server, accessible only to authorized study team members, and retained for the duration required by applicable regulations.

4. **Compensation-** Upon completion of the video call, I will receive $50 (USD) as a thank-you for my time, regardless of my answers.

I am not required to complete this follow-up assessment. If I am not interested in participating, I can ignore or decline the invitation when I receive it. I am also free to decline or stop the activity at any time, without any consequence on my previous involvement in the study or relationship with the study team.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Up to 29 people with a spinal cord injury and 29 companions will take part in this study.

WHO QUALIFIES TO PARTICIPATE IN THIS STUDY?

Inclusion Criteria:

- I must be 18 years of age or older.
- I must be able and willing to attend 9 one-to-two-hour sessions of training.
- I can read, understand, and provide informed consent.
- I am living in the United States and speak English.



WHAT MIGHT MAKE ME INELIGIBLE FOR THIS STUDY?

If any of the items listed below are true for me, I will tell the researcher. To ensure my privacy, I do not have to say which item or items apply to me. If I choose to tell the investigator which items are true for me, the information will not be shared with anyone.

- I am unable to communicate with the device user or trainers due to learning/memory or language disorders
- I have a disease, injury, or other condition that interferes with my ability to complete the study assessments
- I am unable to hold the device steady as determined by study staff
- I do not have the availability to complete the study
- I am enrolled in another study

There is potential risk to the fetus if I fall, my companion falls, or if I sustain some other physical injury while assisting with the use of the exoskeleton. Because of this risk, women of child bearing potential will be required to have a pregnancy test before they can enroll in this study. If I am female, and have a positive pregnancy test, I will not be enrolled.

WHAT RISKS ARE ASSOCIATED WITH PARTICIPATING IN THIS STUDY?

The study described above may involve the following risks and/or discomforts:

- An injury caused by the device in case of loss of balance or fall of the device user while I am assisting them
- Soreness or discomfort from assisting with the device

If I become pregnant during the course of the study, I will notify the principal investigator of this fact as soon as possible since the risks to the fetus or me are unknown.

Risks for the Device User:

- Injury resulting from a fall, including fracture, bruising, muscle and/or joint, or head injury.
- A fracture due to weight bearing.
- Range of motion, muscle, or joint injury due to unintended movement and/or physical constraint
- Skin scratches and injuries at contact points with the device and/or study staff hand placement.
- Muscle soreness, discomfort, or pain in a specific area of the body.
- Changes in their blood pressure.
- Potential for an autonomic dysreflexia (AD—a sudden increase in blood pressure) episode if another medical issue (bowel impaction, full bladder, or pinching of an area of skin, foot, etc.) has occurred.



- A DXA scan carries a small risk associated with low levels of radiation used in the scan.
- An X-ray carries a small risk associated with low levels of radiation used in the scans.
- The device could malfunction.
- Shortness of breath, dizziness, and chest pain or potentially an irregular heartbeat. (If this occurs, the device user and I will make the study staff aware, and the test will be stopped immediately)
- Bowel or bladder activity

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

1. To prevent me from getting hurt by the device being off balance or a fall or by the strain of holding the device, I will learn the correct posture to hold the device safely and comfortably. In case of loss of power, the device's motor's brake system helps me by letting the device fall slowly and gently to the ground, which lowers the chance of getting injured while helping.
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.
   b. The handle on the exoskeleton device will be used by the study staff to provide stabilizing assistance during training, as appropriate.
   c. The device user will be flanked by two study team members, one on each side during all WALK sessions. Study team members will always be by the user's side while they use the exoskeleton device to provide physical support, if needed. The device also uses a system that provides a "safety buffer" that protects the head, neck, and upper body of the device user in the event of a fall. This system includes a rigid, rounded bar above the headrest, two armrests, and a vest with a belt, shoulder straps, and shoulder pads.
   d. A user will never be left unattended when using the exoskeleton device.
3. To minimize the risk of a broken bone in the device users, measurement of the bone mineral density will be obtained as part of the screening for participation in this study. If their bone mass is too low, they will be excluded from the study. In addition, the user will be checked after each task for signs of swelling. If present, the experiment will be discontinued, the user will be instructed to consult with their 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 fitting in an exoskeleton, the device user will be examined at contact points for skin redness, irritation, or breakdown before and after each task. If evidence of skin redness, irritation or breakdown exists, alternate placements for straps and/or padding will be used to protect the area.

If the user in the exoskeleton were to fall and the fall did not cause any harm to them, I will be expected to assist him or her out of the exoskeleton and back into their wheelchair as soon as feasible.

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

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WHAT WILL HAPPEN IF THE RESEARCHERS LEARN NEW INFORMATION ABOUT THE STUDY?

During the course of the study, I will be told about any new findings that might affect my willingness to remain in the study.

WHAT WILL BE DONE TO PROTECT INFORMATION ABOUT ME?

Every effort will be made to maintain the privacy of my study records.

Protected Health Information

The researchers would like to use information about my health as well as information that identifies me. This information is referred to as "Protected Health Information" and is given special protections under The Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996. The researchers must obtain my approval to use Protected Health Information.

If I participate in this research study, information that will be used and/or released may include the following:

- Information about me such as my name, contact information, and age
- Responses to questions about my capacity to assist the device user
- Questionnaires about how I am feeling physically or emotionally
- Other observations made by researchers during the course of the research study

Protected Health Information such as my name, address, date of birth, etc., that is stored electronically is kept in a separate system called the Subject Information Management System (SIMS). SIMS is managed using a database called REDCap. REDCap meets the requirements of laws that protect health information. Access to study data in REDCap will be restricted to members of the study team only. Data are secured by requiring multiple types of login information to reach the study database. REDCap/SIMS also tracks access to and changes made to any records. Kessler Foundation does not permit Protected Health Information to be kept electronically in documents that are not protected in this way in order to ensure my privacy and the confidentiality of my information. Hard copy documents that contain my name, phone number, address, date of birth, etc., are kept in locked cabinets that only members of the research team can access.

Sharing Protected Health Information

My health information may be shared with people and researchers at this institution and associates of the sponsor(s), university, clinic or hospital who help with the research. The researchers may share this information with other people or organizations who are in charge of



the research, others who are helping the research study to be done, those who pay for the research, or those who make sure that the research is done properly.

The study team may share a copy of this approval form and records that identify me with the following people or organizations:

- The Institutional Review Board - a committee that reviews research studies for the protection of the people who participate in research.
- Auditors from Kessler Foundation, the sponsor Wandercraft are responsible for the conduct of research to make sure the researchers are following regulations, policies, and study plans.
- Members of the study team, including LeighAnn Martinez, Suzanne Zuckerman, Courtney Bell, Erica Garbarini, Michelle Agostini, Robert Zeleny, Jonathan Becerril, Manan Anjaria, Mike Kashetta, and Andrew Strumolo.
- The Finance Dept. of the Kessler Foundation, who will prepare subject payments for participation in the study
- Other organizations:
  - FDA (United States Food and Drug Administration) - the government agency that reviews all research information for approval of new drugs and treatments for the public.
  - DHHS (Department of Health and Human Services) - the government agency that oversees and funds research involving human beings.
  - Wandercraft Inc.- the study sponsor and device manufacturer

I have the right to look at my study information at the study doctor's office and to ask (in writing) for corrections of any of my information that is wrong.

If the findings from the study are published, I will not be identified by name. My identity will remain private unless its release is required by law.

Removing Approval

I can change my mind at any time and remove my approval to allow my information to be used in the research. If this happens, I must remove my approval in writing. Beginning on the date I remove my approval, no new information will be used for research. However, researchers may continue to use the information that was provided before I withdrew my approval.

If after signing this form, I want to remove my approval, I can contact the person(s) below. She will make sure the written request to remove my approval is processed correctly.

Gail F. Forrest, Ph.D.
Director, Center for Spinal Stimulation
1199 Pleasant Valley Way
West Orange, NJ 07052
(p) 973.324.3518

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March 11, 2027

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Approval Expiration

This approval has no expiration date. However, as stated above, I can change my mind and remove my approval at any time.

Questions should be directed to the research staff person who is reviewing this form with me. I can also call the Kessler Foundation Privacy Board – *John DeLuca, Ph.D., ABPP at (973) 324-3572.*

WHERE ELSE CAN I FIND INFORMATION ABOUT THIS STUDY?

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 me. At most, the website will include a summary of the results. I can search this website at any time using the NCT# 06814015 to locate this study.

WILL IT COST ANYTHING TO PARTICIPATE IN THIS STUDY?

There will be no cost to me for my taking part in this study, except for any travel-related expenses I might have beyond those reimbursed as described below.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

I will receive $ 25.00 dollars for each visit (up to $225 total) for taking part in this study. I will receive an additional $ 50.00 if I choose to complete the optional follow-up activity.

Participants with SCI and their companions who live too far from Kessler Foundation to commute back and forth each day for their visits may request reimbursement for transportation and accommodation costs up to the maximum amounts shown below. These amounts are for both the participant and companion together, not individually. If I plan to request reimbursement, I should let the study team know before I enroll in the study. Receipts must be provided to receive reimbursement.

- Travel by airfare will be reimbursed up to $400 per round-trip.
- If I travel by car, I will be reimbursed at the IRS rate of $.21 per mile up to a maximum of $151.20 per round trip.
- Hotel costs will be reimbursed at a rate up to $228 per night, for a maximum of 2 nights for individuals with SCI who are screened but not enrolled or for a maximum of 10 nights for enrolled participants.

Note: If I receive $2,000 or more in compensation (not including reimbursements for travel costs) in a calendar year from Kessler Foundation for participation in research, I will have to provide my



social security number to Kessler Foundation before I can be paid due to United States tax laws. I have the option to provide my social security number to the research team now, or wait until it is required for payment and provide it at that time. As described above, many actions will be taken to ensure that the confidentiality of my social security number is protected.

WHAT WILL HAPPEN IF I AM INJURED IN THIS STUDY?

If I take part in this study, I will be exposed to certain risks of physical injury. I may request assistance from the Principal Investigator to arrange medical treatment for any physical injury that occurs as a direct result of my taking part in this study. I understand that I will be responsible for any costs associated with treatment for any physical injury that occurs while I am in this study. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of my medical treatment. I will be responsible for any part of the treatment cost not paid by my insurance or managed care provider. No financial payment is offered to me in the event of physical injuries that happened as a direct result of my taking part in this study.

CAN I CHANGE MY MIND ABOUT PARTICIPATING IN THIS STUDY?

I understand that taking part in this study is my choice, and I may refuse to take part, or may stop taking part in the study at any time without penalty or loss of benefits to which I am otherwise entitled. I also understand the investigator has the right to withdraw me from the study at any time.

WHO CAN I CONTACT FOR MORE INFORMATION?

If I have any questions about my treatment or the research procedures, I can contact:

Gail F. Forrest, Ph.D.
Director, Center for Spinal Stimulation
1199 Pleasant Valley Way
West Orange, NJ 07052
(p) 973.324.3518

If I have medical questions pertaining to this study, there is an on-call resident physician available at the Kessler Institute of Rehabilitation, who can be reached at 973-731-3600. I am aware that this on-call resident physician is not part of the study team and will not be familiar with the study but will be able to direct my study-related medical questions to the appropriate member of the study team.

If I have concerns only regarding my **rights as someone taking part in a research study**, I may contact Donna Servidio, IRB Manager, at 973-965-6672.

I will receive a copy of this consent form if I agree to take part in this research study.

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WILL INFORMATION ABOUT ME BE USED FOR OTHER RESEARCH STUDIES IN THE FUTURE?

The information collected in this research study may be useful in future research studies. The researchers may use or share my information in future research in a way that does NOT identify me without additional informed consent from me. In this situation, the researchers who are using my information do not have access to my name or other identifying information and would not know that I am the person who provided the information. If researchers wish to use or share information or samples that can identify me, they will be required to obtain my informed consent, in writing, for the use or sharing of my information in future research.

SIGNATURE OF PARTICIPANT

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study.

Participant Name:_____Signature:_____

Date:_____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL

To the best of my knowledge, the participant, _____, (or his /her parent/legal guardian) has understood the entire content of the above consent form, and comprehends the study and its risks as well. The participant's questions and those of his/her parent/legal guardian have been accurately answered to his/her/their complete satisfaction.

Investigator Name:_____Signature:_____

Date:_____

SIGNATURE OF WITNESS

I was present when the researcher(s) described the study to the participant (or his/her parent or legal guardian) and I am a witness to the fact that the participant (or his/her parent or legal guardian) consented to participation in this study.

Witness Name:_____

Signature: _____

Date:_____

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