Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Peter Konrad, MD PhD **Revision Date: April 4, 2019**
Study Title: Restoration of Standing and Walking Through ISMS in Humans
Institution/Hospital: Vanderbilt University Medical Center

This informed **screening** consent applies to adults, age 18-50 years old.

Name of participant: _____ Age: _____

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

1. What is the purpose of this screening?

This is a screening to see if you qualify to participate in a study. You are being asked to consider being screened for a study that will test whether electrical stimulation of the spinal cord during surgery can stimulate the muscles in the legs of paralyzed individuals like you. You have expressed interest in participating in this study to be conducted during a surgery you are scheduled to have involving your thoracic spine. In order to decide if you are a candidate appropriate for this study, we will need to ask you many questions involving your medical condition and your upcoming surgery. As such, this is a screening which involves sharing aspects about your medical condition that will be reviewed by the research team and not part of your normal medical care.

The purpose of understanding in detail the nature of your paralysis and any previous treatments is to ensure that any data collected by the research team during the surgery will reflect that you have a complete, and permanent injury of your spinal cord. Many spinal cord injury research studies are performed on partially paralyzed individuals which can make interpretation of any potential therapy unclear as to its effect on the spinal cord. Our intent in this research is to determine the presence of neural circuits in the lower cord that have been completely disconnected from any control from the brain. If true, we intend to continue towards developing of a method to tap into these circuits to restore standing and walking in paralyzed individuals.

Since you are having a spine surgery involving the region overlying these circuits we feel are still present but disconnected from the brain due to the paralysis, we are seeking two volunteers who will allow the research team to test the micro-stimulation of these circuits for up to two hours during the course of your spine surgery. It is very important that we understand in detail the extent of your paralysis and how this segment of your spinal cord is affected by your paralysis in order for the results of the research to be correctly interpreted.

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

This screening will involve detailed questions regarding the nature and extent of your paralysis and any treatment up until now that was involved in the treatment of your paralysis. The screening questions will be administered by members of the research team at Vanderbilt University (led by Dr. Konrad) who are **not** part of the surgical team performing the spine surgery. The questions will initially be conducted by phone with either the clinical study coordinator/research nurse, Wuraola Adesinasi, APRN, or Dr. Konrad (a neurosurgeon and research scientist) at Vanderbilt. If you meet the enrollment criteria, you will then meet with Dr. Konrad and other members of the research team to discuss the details of the proposed study when you arrive to Vanderbilt University for your normal presurgical testing.

The initial questions may take up to one hour by phone or in person. You will not be charged for participating in this screening study. You may decide to quit the screening study at any time without any obligation or effect on your

upcoming spine surgery. None of the information collected will be shared with anyone other than the research team. All efforts will be made to keep your health information private and used only by members of the research team. These members include scientists from Vanderbilt University, Belmont University (Dr. Robinson's Gait lab where you will have baseline Kinesiology measurements collected), and the University of Alberta (Dr. Mushawar's location to review and compare data from the Kinesiology measurements and stimulation during surgery).

Your information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the screening questions. These questions may help us learn more about the causes, risks, treatments involved in the treatment of paralysis.

The answers to these questions may be used to make new products or tests. These may have value and may be developed and owned by the research staff, Vanderbilt University, and/or others. If this happens, there are no plans to provide money to you.

Once you have completed the screening you may be invited to participate in the study, have the study explained in detail, and asked to read and sign the study consent form.

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

There is no cost to you for taking part in this screening.

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

The risk associated with this screening is the loss of personal health information beyond the research team. While all effort will be made to keep the information obtained during this screening within the research team, there is a small and very unlikely risk that the information may be unintentionally released or stolen.

5. Risks that are not known:

Aside from the loss of personal health information, there are no other risks we are aware of that may impact your medical care or otherwise.

6. Good effects that might result from this screening:

a) The benefits to science and humankind that might result from this screening.
There may be no direct benefit to science from your screening but the microelectrode study may provide a first of its kind understanding of whether the paralyzed spinal cord below the injury in humans can be activated by the microelectrode device.

b) The benefits you might get from being in this screening.
Once you have completed the screening you may be invited to participate in the proposed research study on your spinal cord. You may learn more about the status and function of your lower spinal cord below the level of your injury. You may be eligible to participate in these future studies.

7. Other treatments you could get if you decide not to be in this screening:

There are no other treatments available if you chose not participate in this screening. You will continue with your regular medical care and intended spine surgery without any consequences as a result of this questionnaire.

8. Payments for your time spent taking part in this screening or expenses:

There are no payments intended for you as a result in participating in this screening.

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

You may not be able to answer the questions necessary to complete the screening part of the study.

10. What will happen if you decide to stop being in this screening?

If you decide to stop being part of the screening, you should tell your study doctor.

11. 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 **Peter Konrad, MD or study coordinator/research nurse, Wuraola Adesinasi** at **615-343-9822 .** If you cannot reach the research staff, please page the study doctor at **(615-322-5000).**

For additional information about giving consent or your rights as a person in this screening, 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.

12. Confidentiality:

Records and information collected from this screening may include your medical history, medical exams, surgical reports, hospitalization records, images from x-rays, CT, and MRI scans, and the screening questions you will answer. This information will be shared among the research teams at Vanderbilt, Belmont, and the University of Alberta who collectively help decide on the appropriate candidate for the research study.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr Konrad 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.

13. Authorization to Use/Disclose Protected Health

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 screening, Dr. Konrad and his study team may share the results of your study and/or non-study linked medical history, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, Belmont University, University of Alberta and the Food and Drug Administration. 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. Konrad or his study coordinator/research nurse, Wuraola Adesinasi, APRN, in writing and let him know that you withdraw your consent. Dr. Konrad's mailing address *is [Rm T-4224 MCN; Neurosurgery Department; Vanderbilt University Medical Center; Nashville, TN 37232]*. 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 screening, 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 Screening:

I have read this consent form and the research screening 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 Time

Date of IRB Approval: 04/19/2019
Date of Expiration: 12/17/2019

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