Study Title:	Neural Facilitation of Movements in People With SCI
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PI:	Ismael Seáñez
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Washington University in St. Louis

INFORMED CONSENT DOCUMENT- Controls 5 StartReact

Project Title: **Neural facilitation of stimulation-assisted movements in people with spinal cord injury**

Principal Investigator: **Ismael Seáñez, PhD**

Research Team Contact: **Kim Walker, OTD, OTR/L, ATP, (314) 273-7010**

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by **Dr. Ismael Seáñez** having to do with **studying how spinal cord stimulation can facilitate movements after spinal cord injury.** You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to spend **1 visit that will last for 1.5-2 hours.** You will need to come to **Washington University Jubell Hall room 038 on the ground floor.** During that time you will be asked to **attempt different types of movements as electrical stimulation is delivered to your spinal cord and you hear different types of loud noises.** The main risks to you if you participate are **unpleasant or slightly painful feelings from the stimulation or headaches and ear discomfort from listening to loud noises.**

We don't expect this study to benefit you directly, but it will help us understand **whether spinal cord stimulation can be used to improve movement after spinal cord injury.** By volunteering, you may help someone else in the future. There is no cost to you and you will be paid **$10 per hour** for being a volunteer participant. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are a person with no history of any neurological complaints.

The purpose of this research study is to investigate changes the spinal cord with electrical spinal cord stimulation (SCS). Your participation will be used to evaluate whether different types of leg movements are controlled by different neural circuits during spinal cord stimulation. Your participation will also be used to investigate the effects of SCS to enable motor control after SCI.

You are being asked to participate in a study to explore changes in brain and spinal cord activity using reaction time during loud noises (StartReact) as you use your legs to control an assistive device using wearable sensors and non-invasive, transcutaneous SCS. SCS is a safe and non-invasive technique that uses surface electrodes placed on the skin to deliver pulses of electrical stimulation to the spinal cord. The sensation of SCS is a tingling sensation similar to a limb "falling asleep". We will measure movement as you use your legs to control an assistive device using special sensing devices: small infrared markers, video cameras, accelerometers, and electromyography electrodes (EMGs). The StartReact task uses a loud noise as you react to a visual cue to make a movement. We will measure reaction time with different noise intensities.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to participate in this study, you will be asked to come to the Seáñez Lab (Room Jubel #038) located on the ground floor in the Danforth Campus of Washington University in St. Louis, 1 Brookings Dr. St Louis, MO 63130.

Your part in this study will consist of 1 visit that will last for 1.5-2 hrs.

This study does not involve the use of any food or drugs.

1) Study Procedures:

We will use non-invasive spinal cord stimulation to measure how your leg muscles react to the stimulation as you control an assistive device with your legs. We will measure brain, spinal cord, and muscle signals as you perform the different tasks using the StartReact response. The StartReact response is a reaction time response to a loud noise. It uses a loud auditory tone through headphones or a speaker as you are asked to move your legs to react as fast as possible when you see a "go" signal on a computer screen. We will measure how fast you react/move as you are presented with different sound levels, with and without spinal cord stimulation.

Spinal cord stimulation – Non-invasive, transcutaneous spinal cord stimulation will be delivered through surface electrodes placed on your back and on your abdomen. Stimulation pulses will be delivered over the spinal cord using different types of stimuli at 1-100 Hz. Stimulation intensity will be slowly adjusted until a point where muscle responses to the stimulation can be observed. You will be asked to pay attention to all stimuli and provide feedback on your sensation and comfort levels. You are free to ask the experimenter to reduce or stop the stimulation intensity at any point during the experiment.

To measure muscle activity, you will be fitted with surface electrodes (EMGs) placed over your leg muscles. EMGs use electrodes that stick to your skin to measure muscle activity. Shaving of the skin where the electrodes are to be placed is necessary to record high-quality signals. We will use shaving cream to shave the leg areas were electrodes are to be placed and alcohol to clean the skin afterwards.

You are also welcome to shave before your visit. At the end of the day, your legs will be cleaned with alcohol to remove any residue from the electrodes and body lotion will be used to prevent skin dryness and irritation.

Video recordings will be obtained of you as we perform the experiment. This video allows us to measure your leg movements during the experiment. This video will be stored in secure hard drives that only authorized members of the lab will have access to.

Control of assistive device – To familiarize yourself with the device and to adjust the device to your body, you will sit in front of a video monitor and view moving geometrical figures for several minutes. Your lower body and leg movements will change the position of those figures. You will be asked to choose set (4 to 10) comfortable positions of the lower body or to move your legs in any way you choose.

For the control of the control of the assistive device, you will wear special sensing devices: small infrared markers, video cameras, accelerometers. An infrared marker sends invisible infrared light that can be detected by sensors (similar to a TV remote control). An accelerometer is a device that senses motion of a body part (similar to those found on cellphones).

You will be engaged in some of the following tasks: a) practicing reaching movements b) playing videogames c) following a moving target, d) playing a video game.

Throughout your participation in this study, we will monitor you closely for any increased level of stress or other discomfort. Signs such as rapid heartbeat, sweating, agitation, restlessness, or other indicators of discomfort will be monitored. If any such concern should arise, the research procedures will be halted, and clinical staff will be notified.

Will you save my research information to use in future research studies?

We would like to use the movement/muscle data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding brain changes during spinal cord stimulation, or other diseases or conditions, including research to develop investigational tests, treatments, drugs, or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your movement/muscle/brain data, you give up any property rights you may have in the movement/muscle/brain data.

Your data will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available indefinitely for use in future research studies without your additional consent and cannot be removed.

Audio Recording/Video Recording/Photographs

One aspect of this study involves making video recordings and photographs of you. The videos allow us to measure movement of the different regions in the body. Videos will be stored in secure hard drives

that only authorized members of the lab will have access to. Videos will be kept for the length of time required per institutional guidelines, at a minimum.

While all video recordings are stored in a confidential manner, please be aware that the recording will likely contain information that would identify you.

While all photographs are stored in a confidential manner, please be aware that these photographs may include features that could identify you, such as unique tattoos or scars.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 112 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will consist of 1 visits lasting up to 1.5-2 hours.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

1) Potential risks from videogame playing:

Rare

Mild

- Your participation in this study may make you tired (fatigued). To avoid this, trials will be self-paced, and you may ask to have the procedure stopped if you have any discomfort or other concerns.

2) Potential risks from surface electrodes:

Likely / Common

Mild

- Skin redness, dryness or irritation is possible from the shaving and skin preparation required for the application of surface electrodes. After each day experiment, your legs will be cleaned with alcohol to remove any residue from the electrodes and body lotion will be used to prevent skin dryness and irritation.

Rare

Mild

- Skin cuts are possible from shaving. We will use shaving cream to prevent skin cuts and

body lotion after the experiment.

3) Potential risks from spinal cord stimulation:

Likely / Common

Mild

- Unpleasant or even painful feelings could be experienced during spinal cord stimulation. You are free to ask the researcher to reduce or stop stimulation at any point during the experiment.

Rare

Mild

- A mild but unpleasant and potentially painful electrical shock could be experienced during spinal cord stimulation if you accidentally touch the metallic electrode contact. In the event that an electrode becomes disconnected, please do not touch the wires and let the experimenters re-connect the electrodes.

4) Potential risks of StartReact noises:

Likely / Common

Mild

- Loud noises can cause temporary side effects including headache, and discomfort in the ear. These should go away on their own after a few hours. You are free to ask the researcher to reduce or stop stimulation at any point during the experiment.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because we hope that the knowledge gained may help in the treatment of people with spinal cord injury.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to

provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If this is the case, it may take up to 1 month to receive the check. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will be paid $10 for every hour of participation in the study. A prorated rate of $5 dollars for every completed 30 minutes will be used to account for incomplete hours or participation.

If you withdraw from the study, you will be paid for a percentage of the experiment that you participated. The maximum amount of money that you can receive for a visit to the lab is $30. These funds are provided to help support you with time associated with your participation.

WHO IS FUNDING THIS STUDY?

This study is funded in part by the National Institutes of Health (NIH). This means that Washington University is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator Ismael Seáñez at (314) 935-7665 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington**.** If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration.
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research purposes.

- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, your name will not be included in the study database, you will be assigned a unique patient identification number. The research team will make sure information cannot be linked to you. A spreadsheet will be generated which identifies each subject by a unique patient identification number so that HIPAA information will not be disclosed. This spreadsheet will be stored in a HIPAA secure location.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not

discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email and/ or text?

We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Scheduling appointments.
- Recruitment for other research studies in the lab you may fit the eligibility criteria for.

Only the research team will have access to your email and/or text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

Only the research team will have access to your **email and/or text** communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via **email and/or text**.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong **email address and/or phone number**. To avoid this, we will send a test message to ensure we have the correct **email address and/or telephone number**.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

Do you agree to allow us to send your health information via text?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because, in the judgement of the team, it would not be safe for you to continue, because your condition has become worse, because you became pregnant, because funding for the research study has ended, etc.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, or have any illness or injury during your time on this study, you should call us promptly. Kim Walker is the contact person for this research study. You can call her at (314) 273-7010 (Monday through Friday from 9am to 5pm).

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 11/29/23.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)