The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	A user-friendly, non-invasive neuro-orthosis that restores volitionally controlled grasp functions for SCI survivors with tetraplegia
Principal Investigator:	Lauren Wengerd, PhD, OTR/L; David Friedenberg, PhD
Sponsor:	United States Department of Defense, Congressionally Directed Medical Research Programs - Spinal Cord Injury Research Program

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

We are conducting a research study in adults with impaired hand function due to spinal cord injury. We are testing a new investigational 'sleeve' technology called the NeuroLife Sleeve System that you wear on your forearm. The sleeve looks like a compression sleeve and has over 100 electrodes that records your muscles when you attempt to move, and then electrically stimulates the appropriate muscles to help you carry out that movement (e.g., when you attempt to open your hand, the 'sleeve' detects that and then stimulates the muscles required to open your hand). By participating in this 20 week study you will complete a 12-

week rehabilitation training protocol (3x/week, 1-2 hours/session) with our study therapist while wearing the NeuroLife Sleeve System and attempting functional tasks (such as grabbing and releasing a cup) with your hand and forearm. Additionally, you will participate in six sessions where clinical assessments will be conducted to measure your arm/hand function.

1. Why is this study being done?

Ohio State researchers are working with researchers from Battelle Memorial Institute to investigate a new investigational technology in adults with reduced hand function due to spinal cord injury (SCI). This technology is designed to sense what movement you are trying to make (e.g., open your hand), and then electrically stimulates the appropriate muscles to help you carry out that movement. This study will investigate whether this technology can be used to help restore hand function and independence in adults with SCI.

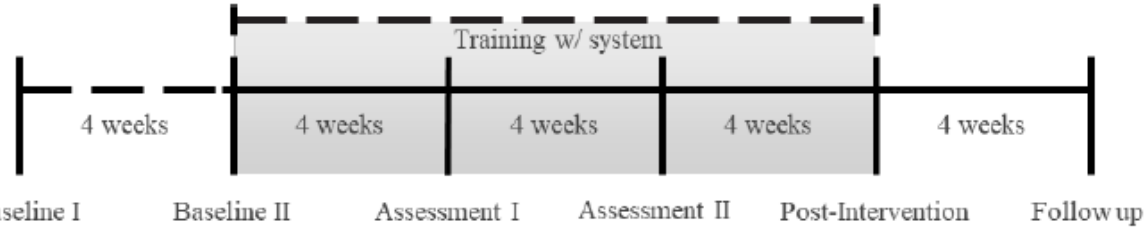
2. How many people will take part in this study?

Up to 12 adults with quadriplegia due to SCI

3. What will happen if I take part in this study?

You will be asked to come to a site at Ohio State or Battelle, both located in central Ohio, for all assessments and study sessions. During the first visit, you will be asked background information about yourself (e.g., age, sex, etc.), medical history, and history of your SCI. We will then complete different clinical outcome measures testing your arm and hand function and strength. For one of these outcome measures, you will wear the NeuroLife Sleeve System to record information about your muscles. We will repeat these tests again four weeks after your first visit, and then you will begin a 12-week rehabilitation protocol using the NeuroLife Sleeve technology with a study therapist. These study sessions will take place over 12 weeks (3x/week, 1-2 hours/session). The NeuroLife system is designed to detect muscles activity of your hand and arm and provides stimulation to those muscles to help them activate. While the device is on, you will be asked to complete 3 different grip and pinch tasks in 20-minute blocks of time with brief rest breaks between. Each rehabilitation training session is expected to take 1-2 hours. The same clinical assessments you did at your first and second visits will again be conducted at 4 weeks, 8 weeks, post-intervention, and 4-weeks post-intervention for a total of six assessment sessions.

Timeline:



4. How long will I be in the study?

You will be in the study for 20 weeks including baseline testing 4 weeks before training, the 12-week training period, and 4 weeks after training has ended. You will participate in a testing session with the outcome measures described above every 4 weeks for a total 6 assessment points. Each testing session can be expected to last approximately 2 hours. The rehabilitation training protocol will consist of three 1-2 hour sessions per week for 12 weeks for a total of 36 sessions. In the event that you need to reschedule sessions (e.g., due to illness or vacation), you may complete up to 2 sessions per day and/or be in the study up to 22weeks to make up those sessions.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

We believe that your participation in this study poses a minimal risk to you, however, it is important that you are aware of potential risks. The initial set-up of the sleeve will require that a very small amount of energy enter your arm to assure that the equipment is working properly. We do not believe that any person would be able to physically feel the energy and it is not likely to harm you in any way. Functional electrical stimulation (FES) is a well-documented, non-invasive and safe application of a mild electrical stimulus to a muscle to help facilitate movement. The risks associated with the NeuroLife EMG-FES System we are investigating are comparable to those associated with traditional FES systems used clinically. The most common risks associated with FES, and thus the NeuroLife EMG-FES System, include skin irritation, muscle spasms, and muscle fatigue or /discomfort (e.g. muscle pain/soreness, tingling, numbness, reduced circulation, swelling, redness). Other risks associated with FES are rare and may include: a "biting, stinging or burning" sensation that feels like the skin is being pinched, nausea, light-headedness, autonomic dysreflexia, dermal burns, joint swelling allergic reaction or infection, and electric shock or burns, and fainting.

It is possible that you could get a rash from the spray, lotion, adhesive, or the fabric sleeve rubbing on your skin. You may also experience minor skin irritation or impressions after wearing the sleeve for an extended period of time. Your skin or hair may be pulled if we attach and remove additional electrodes. These side effects are considered normal and should go away within a few hours. You will have access to an ‘emergency off’ button to stop stimulation. You may press this button at any time for any reason and the stimulation will turn off, or you can notify the system operator to turn off stimulation during the

session. If you have any of the symptoms above, or other discomfort, and it lasts for more than two days please tell us.

If you have an active implantable device (e.g. pacemaker, deep brain stimulator etc.), life-supporting/sustaining device, uncontrolled seizure disorder, are pregnant or planning to become pregnant you may not take part in this study. If you have or develop any skin or orthopedic conditions (e.g. skin irritation, wounds, bone fractures) please inform the study team. Please tell the study team if you develop or are diagnosed with any new health conditions during the study (e.g. compromised circulation, cancer, pressure sores etc.) or if there are any changes in an existing condition you have previously disclosed. Additional risks to study participation are possible in these cases.

There is always a concern about protecting your privacy. We will take appropriate steps to protect your identity and all of the information you share with us. We will let you know in writing if we learn of any new information during the research study that may affect your willingness to be in the study.

7. What benefits can I expect from being in the study?

There may be no direct benefit to you other than the hand/forearm practice you get during activities performed during the training period. There may be benefits to advancing rehabilitation medical device development and research in the future.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

You may incur the cost of transportation and time off work. In many cases parking is free, however, if you incur parking fees to attend study sessions, please let us know and we will provide you with a parking voucher that will cover the parking fees.

10. Will I be paid for taking part in this study?

You will be compensated $75 per assessment session, which will take place six times over the course of the study (up to a maximum of $450). Payment will be made via a reloadable prepaid debit card, following university policies. By law, payments to participants are considered taxable income.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University and Battelle Memorial Institute have no funds set aside for the payment of health care expenses for this study. Your medical or other expenses will be your responsibility or that of your insurance company (or another third-party payer). This does not restrict your right to seek legal assistance. You do not waive any legal rights by signing this form.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information (and bio-specimens) be used or shared for future research?

Yes, your de-identified data may be used or shared with other researchers without your additional informed consent in additional research. Your personal information (e.g., name, phone number, date of birth, etc.) will not be shared with anyone outside of our study team. Any data shared will be linked to you only by a unique subject identification number. This may include sharing scores to your clinical assessments and basic information about your spinal cord injury with the manufacturers of the Toronto Rehabilitation Institute Hand Function Test (TRI-HFT) as they may use this data for further analysis. Data will be shared across Ohio State and Battelle study teams through secure, access-controlled electronic repositories.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsors (Ohio State University and Battelle) supporting the study, their agents or study monitors; and
- representatives of the Department of Defense (DoD) will have access to, and are eligible to review, your research records as this is a DoD-funded study.

Authorized Ohio State University and/or Battelle staff not involved in the study may be aware that you are participating in a research study and have access to your information.

If we find information that significantly impacts your health, we **will** share it with you. We will verbally report to you during your last study session (12-Week Post-Assessment) your scores on relevant clinical outcome measures over the course of the study for your awareness.

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 you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:

Physical exams
Laboratory, x-ray, and other test results
Diaries and questionnaires

- Records about the study device
- Videos and pictures from study sessions

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others: Authorized Battelle staff

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact Dr. Lauren Wengerd (call/text: 330-464-9171; lauren.wengerd@osumc.edu) or Dr. Dave Friedenberg (call/text: 513-509-6809; friedenbergd@battelle.org).

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact Kathleen Ojala at 614-293-6482.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Ohio State Office of Responsible Research Practices at 1-800-678-6251 and/or the Battelle Human Protections Administrator at 614-424-7648.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Jan Schwab (call: 614-685-9278;

jan.schwab@osumc.edu), Dr. Lauren Wengerd (call/text: 330-464-9171; lauren.wengerd@osumc.edu), or Dr. Dave Friedenberg (call/text: 513-509-6809; friedenbergd@battelle.org).

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time