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| **Official Title:** | High-density EEG in Neurological Disorders |
| **NCT number:** | NCT04266041 |
| **Document Type:** | Informed Consent – Peripheral Nerve Arm |
| **Date of the Document:** | 05Jan2024 |

**CONSENT TO TAKE PART IN RESEARCH**

*Dartmouth-Hitchcock Medical Center*

*Study title:* High-density EEG in Neurological Disorders

*Principal Co-Investigators:* Yinchen Song, PhD and Krzysztof Bujarski, MD

**You are being asked to take part in a research study. Taking part in research is voluntary.** This study will use measurements of brain waves using a novel method called high-density EEG to locate and map out the brain areas responsible for important functions such as movement, language, sensation and memory. You are being asked to participate in this study because you have peripheral nerve dysfunction and the high-density EEG will be recorded and may help your doctors understand the extent of injury and assess the function recovery. Your decision whether or not to take part in this study will have no effect on the type of medical care that you receive. Please ask questions if there is anything about this study you do not understand.

**What is the purpose of this study?**

The purpose of the study is to use a new method of EEG recording to better understand important brain areas in movement and sensation. In addition, this new method of EEG recording will allow us to understand how the peripheral nerve dysfunction could affect the central nervous system.

**Will you benefit from taking part in this study?**

You might not personally benefit from being in this research study. Your participation will help us to improve and check the accuracy of our testing procedures for mapping brain functions, which should lead to improved care of future patients.

**What does this study involve?**

If you agree to participate is this study, you will be asked to complete two to four 60-120 minute EEGs with a high-density EEG cap. The cap fits on your head just as a hat would. During the recording, we may ask you to rest, try to sleep, or to participate in a task. The tasks allow us to understand which regions of the brain are important in movement and sensation. The first EEG session will be done before your surgical procedure, and the other sessions will be at post-operative follow-up visits to assess the peripheral nerve function recovery.

In the following list, we have marked (**with initials**) those additional tasks which we would like to carry out in your case:

___ 1. Recording from brain areas involved in movement.

We will ask you to make simple, repetitive movements of fingers, feet or eyes.

___ 2. Recording from brain areas involved in sensation.

We will simulate the nerves in your arms and legs through sticky pad electrodes to map your somatosensory area (brain region that control your sensation of your arms/legs). You will be asked to keep still with eyes closed. You might feel some twitching sensation on your arms/legs.

**What are the options if you do not want to take part in this study?**
Participation in this study is optional.

**If you take part in this study, what activities will be done only for research purposes?**
All of the above procedures are for research purposes.

**What are the risks involved with being enrolled in this study?**
This study poses few risks. The EEG cap used during the recording is approved for clinical use. It is not an invasive procedure. Any equipment used in your testing will be electrically isolated.

For the sensory task, we will use some non-invasive sticky pad electrodes to stimulate your peripheral nerve at a minimum current. You might feel some twitching sensation on your arms or legs. Normally you will not have any pain or numbness as a result of the peripheral nerve stimulation. If you experience any discomfort from the stimulation, we can stop the task at any time. Although rare, there is a potential for the sticky pad electrodes to cause mild irritation to delicate skin. Let us know if you have an allergic reaction to adhesives or tapes.

**Other important items you should know:**
- **Leaving the study:** Your decision whether or not to participate in this study, or a decision to withdraw will not involve any penalty or loss of benefits to which you are entitled. You may choose to stop your participation in this study at any time. If you choose to withdraw from the study, you may revoke your approval for the use of your medical information. To do this you may contact the researcher in writing.
- **Number of people in this study:** We expect 20 subjects to enroll in this study here.
- **Funding:** There is no outside funding for this research project.

**How will your privacy be protected?**
The data collected in this study will consist primarily of EEG data that would be recorded along with timing and performance data when tasks are being done. We will also utilize a standard brain MRI atlas to assess the anatomical localization of the EEG data. We may utilize your routinely obtained imaging data (MRI, CT) of your brain to assess the anatomical localization of the EEG data more accurately. Data gathered in the course of this study will be maintained indefinitely or as required by federal or state regulations. Every effort will be made to protect the identities of the participants and the confidentiality of the research data used in this study. The research team may share de-identified EEG and imaging data collected for this study with other institutions. This de-identified data may be added to public databases of EEG data. All other data will be used by the research team for purposes as described in this form.

**Who may use or see your health information?**

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at Dartmouth-Hitchcock Medical Center and elsewhere. You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center

In order to conduct this study, researchers need to use your health care information. This data is called Protected Health Information ("PHI"). PHI is protected by federal privacy laws (HIPAA). By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. There is no intention to disclose your PHI to others outside of the study. There are protections in place to keep your PHI and research data confidential. However, HIPAA requires notification so you are aware *if your* PHI is disclosed to others, it may no longer be protected by federal privacy laws.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Identifiable data collected for this study will be used for research purposes which are determined to be reasonable and in line with expectations by a review committee.

Once data collected for this research study is no longer identifiable, the data may be used or disclosed for other purposes.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. You have a right to receive a copy of the information in your medical record at any time.

It is possible for a court or government official to order the release of study data including information about you.

**What if you decide not to give permission to use and share your personal health information?**

If you do not allow use of your health information for this study, you may not take part in this study. If you choose to stop taking part in this study, you may cancel permission for the use of

your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

**What about the costs of this study?**
There will be no costs to you for participating in this study.

**Will you be paid to take part in this study?**
You will not be compensated for your participation.

**What happens if you get sick or hurt from taking part in this study?**
If you are injured or become ill as a result of research procedures, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment.

- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- Trustees of Dartmouth College

If you have any questions or concerns about the legal responsibility of these organizations, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at (603) 653-1250 during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

**Whom should you call with questions about this study?**
If you have questions about this study or concerns about a research related injury, you can call the research director for this study: Dr. Yinchen Song (603-650-8402) or Dr. Krzysztof Bujarski (603 653-6118) during normal business hours.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (603) 650-1846 or irb@hitchcock.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

**CONSENT**

I have read the above information about High-density EEG in Neurological Disorders and have been given time to ask questions. I agree to take part in this study and I have been given a copy of this signed consent form.

_____

Participant's Signature Date PRINTED NAME

If participant has impaired decision-making capacity, please complete as appropriate:

_____

Participant's name

_____

Signature of legally authorized representative Date PRINTED NAME

_____

Researcher or Designee Signature Date PRINTED NAME