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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. In addition, this study will use measurements of electrical impedance to sense and image the electrical properties of brain tissue using methods called Electrical Impedance Sensing (EIS) and Electrical Impedance Tomography (EIT), respectively. You are being asked to participate in this study because you recently had a stroke. The high-density EEG will be recorded and may or may not help your doctors determine the most effective treatment for you. Your decision whether or not to take part 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 1) to use a new method of EEG recording to better understand which part of your brain is being affected and 2) to evaluate how EIT and EIS might be used alone or combined with EEG to identify and characterize brain lesions and neurologic disease. In addition, this new method of EEG recording will allow us to map important brain areas in movement, sensation, language, thinking and cognition.

Will you benefit from taking part in this study?

You might not personally benefit from participating in this research study. The testing procedures we are using are in the research stage and may not provide your doctors with information that would affect your diagnosis and treatment. Your participation will help us to determine and improve the accuracy of our testing procedures for mapping brain functions and for imaging and characterizing brain lesion tissue electrical properties, which will hopefully lead to improved care of future patients.

What does this study involve?

If you agree to participate in this study, you will be asked to complete a 90-120 minute EEG recording using a high-density EEG cap. Special types of photographs of the EEG cap, electrodes, and your head will be taken. These photographs will allow us to produce more accurate results by knowing precise locations of electrodes. The photographs will be stored in password-protected computers and will not be shared with outside parties. During the same session electrical impedance data will also be recorded from the EEG cap electrodes and up to 30 additional EIS electrodes. The cap fits on your head just as a hat would. During the recording, we will ask you to rest, try to sleep, and to participate in the following tasks: viewing pictures, answering questions, speaking, or moving your arm or leg. The tasks allow us to understand which regions of the brain are important for speaking, movement, sensation

cognition, and other functions. The additional EIS electrodes include 1) standard EEG electrodes placed on the scalp between the electrodes already on the EEG cap, 2) custom electrodes placed on the skin around your eyes (your eyes will not need to be closed), and 3) soft-palate electrodes incorporated into a custom-built mouth guard (to be used once in the beginning and once at the end of the period of data acquisition).

We would like to carry out a recording from your resting-state brain (EEG). We will ask you to rest and try to fall asleep. The session may last 90-120 minutes depending on your specific situation.

At your next regularly scheduled visit (2-3 months from now), we may like to do a second data collection. We would like to repeat the recordings noted above and perform an MRI brain scan. The MRI may be essentially identical to the one you may have had as part of your regular clinical care. The MRI scan will take approximately 60 minutes.

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 speech (EEG).
We will ask you to repeat words, or answer simple questions.

___ 2. Recording from brain areas involved in movement (EEG).
We will ask you to make simple, repetitive movements of fingers, feet or eyes.

___ 3. Recording from brain areas involved in sensation (EEG).
We will stimulate 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 remain still with your eyes closed. During stimulation you might feel a twitching sensation in your arms/legs.

___ 4. Recording from brain areas involved in vision (EEG).
We will use a computer monitor to present pictures such as shapes, colors, or objects such as faces. You may be asked to make simple choices about these pictures and to indicate your choice by pressing buttons or by counting.

___ 5. Recording from brain areas important for memory (EEG).
You will perform a series of tasks which require you to make choices about words or figures, or to decide whether a word or figure has already been seen or heard.

___ 6. Recording from areas important in social and emotional processing (EEG).
We will use a computer monitor to present pictures and videos of people engaged in social interaction, as well as standardized tasks designed to understand the nature of emotions. Some of these images may be emotionally disturbing. If you are not comfortable viewing such images, please do not participate in this study. You can withdraw from the study at any time.

___ 7. Recording from areas important in auditory processing (EEG).
We will use a speaker to play music or ambient noise in front of you to understand how the auditory cortex is connected within brain networks.

___ 8. Electrical Impedance measurements from the EEG cap in a resting state (EIT).

We will ask you to rest while the electrical impedance data are collected over ~10 minutes.
___ 9. Electrical Impedance measurements from the EIS electrodes. You will be shown the electrodes and we will request feedback about the comfort of their use following data collection. During collection we will ask you to rest or begin the first EEG task described above for ~30 minutes (EIS).
___ 10. MRI brain scan at the follow-up session, if possible.

What are the options if you do not want to take part in this study?
Participation in this study is optional. If you choose not to participate in this study, we will carry out your evaluation and treatment using previously established methods.

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, relatively minor 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 your safety and arranged to eliminate the possibility that you would be injured. If you have a known history of seizures, our experimental testing will be temporarily suspended if you have a seizure, and indefinitely suspended if you are having a flurry of seizures or don't feel able to continue. Experimental testing would only be resumed when you feel able to do so, are willing to do so, and your doctors agree that it is advisable. Some of the pictures shown to you in the tasks may be considered emotionally disturbing. If you have any objection to the pictures the video or the memory testing, you can withdraw from the study at any time.

For the sensory task, we will use some non-invasive sticky pad electrodes to stimulate your peripheral nerve at the minimum necessary current. You might feel some twitching sensation on your arms or legs. Normally you should not experience any pain or numbness as a result of the peripheral nerve stimulation. If any discomfort from the stimulation occurs, 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 beforehand if you have ever had an allergic reaction to adhesives or medical tape.

The risk associated with the electrical impedance measurements (EIT & EIS) is expected to be small. It is important to know that the device and imaging are experimental and it is always possible that unexpected effects, which have not been observed previously, may occur. There is the risk of electrical shock, due to the application of electrical currents to your body. Our experience with this device demonstrates that this risk is very low and not common, since our equipment is designed to apply less than 10 milliamps of current, which is less than that injected when placing a standard 9-volt battery on your skin. It is possible, but unlikely, you might feel a slight tingling sensation where the electrodes touch your skin. This current conforms to the allowable current injection limits specified by US and International standards

of safety for medical devices. Should you ever feel any discomfort we can stop the study at any time.

The known risks of an MRI scan are minimal. Implanted medical devices and metallic fragments inside your body may pose a risk if you were to enter the MRI magnet room. Therefore, questions regarding medical and work history will be asked prior to your exam. No magnetic metal objects are allowed to be brought into the magnet room at any time except by approved personnel.

There is no known health risk associated with exposure to magnetic fields during an MRI. There are minimal risks from the loud noise associated with the MRI scanner and from the discomfort of lying on a hard surface. We shall provide you with protective earplugs as necessary and make every attempt to ensure your comfort with blankets, etc. during your time in the scanner.

All MRIs will be reviewed by a radiologist to look for any unexpected findings in your brain scan. Should this occur, the findings will be considered by the appropriate personnel and the study doctor will inform you if necessary.

If you are not able to have an MRI for any reason, you will still be able to participate in this study.

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. Your decision to stop your participation will have no effect on the quality of medical care. 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 50 patients with a stroke to enroll in this study at DHMC.

• **Funding:** This study is funded by a Hitchcock Foundation Pilot grant and a Dartmouth College Innovation Fellowship.

How will your privacy be protected?

The data collected in this study will consist primarily of EEG and electrical impedance data that would be recorded along with timing and performance data when tasks are being done. We will also utilize your routinely obtained imaging data (MRI, CT) to assess the anatomical localization of the EEG and electrical impedance data, and compare our mapping results to other forms of functional assessment data obtained as part of your diagnostic workup. Any photographs taken will be deleted from the scanning device as soon as they are transferred to password-protected research computers.

Data gathered during 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, electrical impedance, and imaging data collected for this study

with other institutions. These 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?

Participants will be compensated $25 for each testing session.

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
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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 the High-density EEG in Neurological Disorders study 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