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CONSENT TO PARTICIPATE IN RESEARCH

Dartmouth-Hitchcock Medical Center

Microelectrodes in Epilepsy

Introduction: You are being asked to participate in a research study. Your participation is voluntary.

You are being asked to participate in this study because you have been diagnosed with epilepsy and require intracranial EEG monitoring prior to epilepsy surgery in order to better understand where your seizures are coming from. Your decision whether or not to participate in this study will have no effect on the quality of medical care or the type of treatment that you get for epilepsy. Please ask questions if there is anything you do not understand.

What is the purpose of this study?

This study has two purposes. The first purpose of this study is to see if a new type of EEG electrode can help us to determine where your seizures are coming from in your brain. The second purpose of this study is to see if the new type of electrode can help us to determine what type of brain functions are performed by the brain tissue that is causing your seizures. This goal of this study is to better understand where the seizures are coming from and to avoid or minimize causing thinking, memory, or speech problems as a result of epilepsy surgery.

Are there any benefits from participating in this study?

The usefulness of the new electrodes is not well understood. Therefore, there is only a small chance that the new type of electrode will benefit you directly. In other words, there is little chance that the new electrodes will help us to make a decision of what type of surgery you get. In general, the study is designed to gather information that may help people in the future.

What does this study involve?

The new electrodes that we will be testing are similar to the standard electrodes. The difference is the addition of ultra-thin electrodes called microelectrodes to the standard large electrode. The ultra-thin addition will allow us to record from smaller regions of the brain. The new electrodes are FDA approved for this use. The new electrodes have been previously tested on 24 participants.

Your participation in this study will last the duration of your intracranial EEG recording which usually requires about 10 days of hospitalization. In addition to the standard intracranial EEG recording, we will be intermittently recording additional signal using the new electrodes. You will not notice any differences from standard recording when we do this. You will also be asked to participate is a variety of memory, speech, or thinking tasks during

the time that you are recording. Each task may last as much as 60 minutes and will occur several times during the hospitalization. Once the intracranial EEG monitoring is over, the study will be complete and there will not be any further requirements.

How is this different from what will happen if you do not participate in this research?
Not participating in this research will not affect the type of care that you get. You will get the standard intracranial EEG monitoring. If you enroll in this study, additional recording and additional memory testing will be given to you while you are in the hospital.

What are the risks involved with being enrolled in this study?
There are no known risks to you from these new electrodes as compared to the standard electrodes. Significant complications from standard intracranial EEG monitoring occur in about 5% of patients and include but are not limited to bleeding and infection. To the best of our knowledge, the risk of complications from these new electrodes is the same as from the standard electrodes. The new electrodes are designed to mimic the standard electrodes with the exception of the addition of the microelectrode contacts.

Other important items you should know:
• 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 will not receive any compensation if the results of this research are used towards the development of a commercially available product.
•To the best of our ability, any significant new findings during this research study will be made known to you. You can then decide if you want to continue in this study.

• **Withdrawal from the study:** You may choose to stop your participation in this study at any time before the insertion of the electrodes. Once the electrodes are inserted, they cannot be removed or changed except at the end of the monitoring session. If during the session, you choose not to participate in the memory and language testing, you may choose not to do so.

• **Funding: The** Department of Neurology and the National Institute for Neurological Disorders and Stroke (NINDS) provide funding to Dartmouth-Hitchcock Medical Center (DHMC) for this research.

• **Number of participants:** We expect multiple participants to enroll in this study. The full number is not certain at this time and depends on the findings.

How will your privacy be protected?
The information collected as data for this study includes:

- your name, medical record number, date of birth, age, left or right handedness, age of seizure onset, types of seizures, frequency of seizures, and history of medical treatment

- results of standard tests and imaging such as MRI (magnetic resonance imaging), SPECT scans (single-photon emission computed tomography), PET imaging (positron emission tomography), Wada testing, neuropsychological evaluations, scalp EEG (electroencephalogram) monitoring, and standard intracranial EEG monitoring
- results of memory, thinking, and speech tests specially designed for this study
- brain activity detected using the microelectrodes.

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential.

All data that includes information that identifies you will be kept confidential and available only to the doctors involved in your care and researchers participating in this study. Study data will be kept on secure password-protected computers. Published results from the study will not include your name or other identifying information.

The information collected for this study will be used only for the purposes of conducting this study.

Who may use or see your health information?

By signing this form, you are allowing the research team to use your health information and disclose it to others involved in the research. The research team includes the researcher directing this study plus the people working on this study at DHMC and elsewhere. You are also permitting any health care provider holding your health information needed for this study to give copies of it 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

Your permission to use your health information for this study will not end until the study activities by the research team are completed. During this study, participants may not have access to the study data. You may request study data once the study activities have been completed.

During this study, information that identifies you may be given to some organizations that may not have a legal duty to protect it. These organizations may also use and disclose your information for other purposes.

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 participate 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 in writing that you are cancelling your permission. Information collected for the study before your permission is cancelled will continue to be used in the research.

Whom should you call with questions about this study?

Questions about this study may be directed to your doctor or to the researcher in charge of this study: Dr. Jobst at 603-653-6118 during normal business hours. If Dr. Jobst is not available, other persons that are involved in the study will be available to answer your questions. If you would like to contact a physician after hours with regards to this study, please call the DHMC main number at 603-650-5000 and ask to speak to the neurology resident on call.

If you have questions, concerns, or suggestions about human research at Dartmouth, you may call the Office of the Committee for the Protection of Human Subjects at Dartmouth College (603) 646-3053 during normal business hours.

What about the costs of this study?

The cost of the research microelectrodes for this study will be covered by the Department of Neurology and NINDS. Insurance companies or other third party payers will not be billed for research procedures that are not standard of care. The rest of the medical care that you will receive in this study is considered standard care for your situation and thus would be recommended regardless of your decision to participate in research. These costs will be billed to you or your insurance carrier.

Will you be paid to participate in this study?

No.

What happens if you get sick or hurt from participating in this study?

SPONSOR POLICY: The sponsors of this research are the Department of Neurology and the National Institute of Neurological Disorders and Stroke (NINDS). If you develop an illness or an injury happens because you are in this research study the Department of Neurology and the NINDS will not be responsible for the costs that are required to treat you.

DHMC POLICY: It is DHMC policy that if you are injured or become ill as a result of research procedures, medical treatment will be provided to you but DHMC will not pay for this treatment.

If you have any questions or concerns about the legal responsibility of DHMC, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at 603-650-7864 between the hours of 8:00 A.M. and 5:00 P.M. on Monday through Friday.

CONSENT

I have read the above information about Microelectrodes in Epilepsy Surgery and have been given an opportunity to ask questions. I agree to participate in this study and I have been given a copy of this signed consent document for my own records.

Participant's Signature and Date PRINTED NAME

OR

Court Appointed Legal Guardian and Date PRINTED NAME

Researcher or Designee Signature and Date PRINTED NAME