Official Title:	Neuromodulation of affective valence in humans by amygdala stimulation
NCT number:	NCT 05292183
Document Type:	ICF
Date of the Document:	05/09/2023 Version Date

Title of research study*:* Neuromodulation of affective valence in humans by amygdala stimulation

Investigator: Krzysztof A. Bujarski, MD

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

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have seizures, and your brain waves (EEG) are being recorded to help your doctors decide the most effective treatment for your seizures.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research is being done to understand how the brain processes emotions. We want to see how the brain responds when a person sees pictures which portray either emotionally positive or negative content. We also want to determine how small amounts of electrical stimulation which you do not feel influence your perception of these images. We hope this research will help provide new treatments for disorders such as anxiety, aggression, and post-traumatic stress disorder.

How long will the research last and what will I need to do?

During the course of your admission, you will be asked to participate in 1 -2 (60 minute) daily testing sessions per day.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

This study does not have any significant risks beyond those that are normal when you are monitored with video/EEG equipment to diagnose your seizure disorder. Study testing will be temporarily stopped if you have a seizure, and stopped entirely if you are having a flurry of seizures or don't feel able to continue. Study testing would only be restarted when you feel able and willing to do so, and if your doctors agree that it is advisable.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

You are not likely to benefit from being in this research study. This research may benefit patients in the future. As mentioned above, we hope this research will help provide new treatments for disorders such as anxiety, aggression, and post-traumatic stress disorder.

What happens if I do not want to be in this research study?

Participation in research is completely voluntary. You can decide whether to participate or not. You will receive the same care in either case.

Detailed Information: The following is more detailed information about this study, in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Kris Bujarski, MD (603) 653-6118 during normal business hours. If Dr. Bujarski is not available, other members of the Department of Neurology will be available by calling (603) 650-5000 (24 hours) and asking for the neurology resident on call.

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.

How many people will be in this study?

We expect about 16 people to be in this research study.

What happens if I say yes, I want to be in this research study?

If you agree to participate is this study, we will perform one or more study tasks to help us understand how the brain processes emotion and how stimulation effects emotional processing.

You will be asked to participate in 1-2 (60 minute) daily testing sessions per day during the course of your admission. During each testing session, the study tasks will last up to several minutes each, and will require you to view pictures while EEG recordings are made from the electrodes placed in your brain. Your routine video/EEG monitoring and brain function testing should not be disrupted or prolonged by our study testing, and if you have a seizure during our testing, it will be recorded as usual for review by your doctors.

Below are the study procedures which we wish to carry out in your case:

1. Recording from areas important in social and emotional processing.

We will use a computer monitor to present pictures and videos of people engaged in social interaction, and present well 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.

2. Using brain stimulation to map function of certain parts of your brain.

We will use a brain stimulator—normally used to map where important brain regions are located—to understand new functions of the brain. You will be presented with pictures on a computer screen. As you view these pictures, the brain stimulator may be activated (this is not something that you feel) and you will receive electrical stimulation through these electrodes delivered to specific regions of the brain. We will be measuring how brain stimulation may affect your emotional response to a specific stimulus.

3. Completing The Emotion Self-Rating Scale (ESR).

This questionnaire will be given to ensure the stimulation doesn't increase any unpleasant emotional experience for you. This will take place electronically (on a computer screen) and will be administered before and during stimulation of a specific part of your brain.

What are my responsibilities if I take part in this research study?

If you take part in this research, you will be responsible to:

Your responsibilities as a person taking part in this study

(1) Be aware it is important for your safety that the research team knows about your medical history and current condition.
(2) Notify the research team in advance if you plan to undergo any other medical treatment during this study or are taking or plan to start taking any medications.
(3) Notify the research team immediately if you suffer any injury or unexpected reaction to the study procedures.
(4) Seek treatment with the help of the research team if you suffer any injury or unexpected reaction to the study procedures.
(5) Make reasonable efforts to follow the instructions of the research team.

What happens if I say yes, but I change my mind later?

You can leave the research at any time, and it will not be held against you. If you decide to leave the research, contact Dr. Bujarski so that you can be removed from the study. Information collected for the study before your permission is cancelled will continue to be used in the research.

Is there a possibility being in this study could be bad for me or harm me? (Detailed Risks)

Although all efforts will be taken to ensure safe stimulation parameters, untoward effects of electrical stimulation are the main potential risk. Risk of electrical stimulation includes seizures and stimulation-induced symptoms such as nausea or tingling.

We believe this risk will be minimal. Electrical stimulation is used frequently in patients like you who have intracranial electrodes. For this study, a physician will be present at all times during stimulation.

There will also be epilepsy nurses available to administer rescue medication, if necessary, after a seizure.

The second potential risk to you is viewing of emotionally provoking images. This image set is composed of emotional images similar to PG-13 rated movies. Your participation in the study may be stopped if you feel uncomfortable viewing any images.

There is a slight risk of a breach of confidentiality by taking part in this study. Your participation in this study is considered confidential and records identifying you will be kept as confidential as possible under the law.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

This study is federally funded by NIH, and compensation for a research-related injury or illness is not provided by federal law.

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
- National Institute of Health
- National Institute of Mental Health
- The Food and Drug Administration

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.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The data collected in this study will consist primarily of EEG data that would be recorded along with timing and performance data when functional tasks are being done. We will also utilize your routinely obtained imaging data (MRI, CT) to assess the anatomical localization of the EEG data, and compare our mapping results to other forms of functional assessment data obtained as part of your diagnostic workup. Data gathered throughout this study will be maintained for 10 years or as required by federal or state regulations.

If identifiers are removed from your identifiable private information and the data points such as EEG recordings, questionnaire results, MRI, and CT that are collected during this research, that information or the collected data could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Federal law provides additional protections of your medical records and related 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
- The Dartmouth-Hitchcock Health Institutional Review Board (D-HH IRB)

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 that 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.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if it is deemed unsafe to proceed with recording or stimulation.

To the best of our ability, any significant new findings during this research study will be made known to you. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the National Institutes of Health (NIH).

Instead of being in this research study, you may choose not to participate in this research study.

Your information and the collected data (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this

happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

The monitoring and treatment that you will receive at DHMC is considered the standard care for patients with your type of epilepsy and thus would be recommended regardless of your decision to participate in research. Your participation in this study would not lengthen your hospital stay or affect your charges for clinical care. The costs of the standard clinical monitoring and treatment will be billed to you or your insurance carrier.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	