Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Optimizing Transdiagnostic Non-invasive Vagus Nerve Stimulation to Enhance Learning

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Your participation is entirely voluntary. This is a research study to find out if learning is affected by stimulation to the ear and to determine the best dose time.

If you agree to participate, you will be asked to complete questionnaires online which will take about 30 minutes. Then you will be asked to the lab to receive ear stimulation while brain activity and other body responses (e.g., heart rate) are measured with sensors that will be placed around your eyes, on your hands and near your collar bone. Pupil dilation also be measured with a camera. During the ear stimulation you will be asked to look at scenes on a computer and listen to tones. This will take place during one lab visit lasting about 2.5 hours, and you will be asked to sleep as usual and refrain from caffeine, tobacco, substance, and alcohol use prior to coming to the laboratory

It is unknown if ear stimulation will help your condition, so there are no direct benefits to you. This intervention could help people in the future with more research. Risks include: mild discomfort answering the survey items and from measuring your body responses, such as mild irritation or redness after sensor stickers are removed. The ear stimulation may result in redness and some discomfort, such as a “tickle” or “pricking” sensation. You do not have to participate in this study if you have a condition you are seeking treatment for. Alternative treatments for mental health concerns include therapy/counseling or psychiatric medication.

If you are interested in learning more about this study, please continue reading below.

A. PURPOSE OF THE RESEARCH

The purpose of this study is to determine how ear stimulation affects learning and brain/body responses. The goal is to determine how long ear stimulation should be delivered to determine the best changes in learning and bodily responses. You are being asked to volunteer in this study because you expressed interest in participating. To meet these goals ear stimulation will be delivered for 90 minutes, while sensors

measure your brain and body responses. Pupil diameter will be measured. During these procedures you will be asked to watch scenes and listen to different tones.
This research involves an investigational treatment which is not currently FDA approved. The device being used to deliver ear stimulation is called the **Digitimer DS7A High Voltage Constant Current Stimulator**, which is an FDA cleared medical device.

The study is being done at the Institute of Psychiatry at MUSC. Approximately 90 people will take part in this study. An internal MUSC grant will sponsor this study. The investigator in charge of this study at MUSC is Danielle Taylor, Ph.D.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will be asked to complete surveys about your background information, thoughts, emotions, and behaviors before coming to the lab. These will include questions about anxiety, childhood and adult trauma, emotional experiences, thought patterns, and health behaviors you may or may not have.
2. You will be asked to sleep as usual and refrain from caffeine, tobacco, substance, and alcohol use prior to coming to the laboratory.
3. When you arrive to the lab, if you are able to bear children, you will be asked to take a pregnancy test, because the risks of ear stimulation to a fetus are currently unknown. This test will be provided to you at no cost. Should the test present a positive result, the study will discontinue at no consequence to you.
4. Sensors will be attached to measure eye movement, heart rate, sweat responses. These sensors that will be used in this study are placed on top of the skin with a small sticker. These will be placed around your eyes, on your fingertips, collarbone, and on your ribcage, and will be used to see if ear stimulation affects heart rate or sweat responses.
5. Brain activity will be measured using electroencephalography or EEG. An elastic cap (like a swimmers cap) with sensors attached will be placed on your head. A water-based gel will be used in your hair, so that we may measure brain activity. This gel rinses out with water. EEG will be used to determine how ear stimulation affects brain activity.
6. A device will be set up to measure the dilation of your pupils. This will be measured to determine how ear stimulation affects pupil dilation which is linked to emotional responding.
7. Electrodes will be attached to your ear with a small sticker or clip, which will deliver mild stimulation. These electrodes will be plugged into the Digitimer DS7A High Voltage Constant Current Stimulator, which is a device that delivers transcutaneous auricular vagus nerve stimulation or taVNS. We use a stepped approach to gradually increase stimulation until you can feel it. Stimulation will be

delivered randomly to either your ear lobe and/or your tragus (the small cartilage knob before the ear canal) for 90 minutes.

8. While the heartrate, eye movement, and brain electrodes are attached you will be asked to watch neutral short films while tones are played through head phones. These tasks will affect brain activity and other responses and will allow researchers to determine how ear stimulation affects attention.
9. You can discontinue your participation of this study at any point without consequence.

C. DURATION

Participation in the study will take 1 in person visit lasting about 2.5 hours. You will be sent surveys before you come to the lab which will take no more than 30 minutes to complete.

D. RISKS AND DISCOMFORTS

There are risks to the participation in this study.

Surveys: You may experience some mild discomfort while answering some of the questions in the survey part of the study, as they ask about personal topics.

Brain Activity and Body Responses: Small circular stickers are used to attach sensors on the skin. Removal of these adhesives may result in mild local irritation or redness. A water soluble gel which contains salt is used to collect EEG/brain activity, but this gel does not cause irritation. This gel rinses easily with water, though some people dislike having the gel in their hair. In rare cases mild electrical discharge may occur due to static electricity while brain activity is measured. This is not common, but it can occur in unusual circumstances, such as when touching metal objects. These shocks are similar to static shocks that result from articles of clothing and contact with other individuals or metal materials. EEG does not make electricity – it only measures naturally occurring electricity the brain produces.

Ear Stimulation: The ear stimulation delivered during the study is not invasive, but includes risk. Researchers at MUSC and other universities have shown it is safe. However, it is still being investigated. Others who have received ear stimulation state that it feels like a “tickle” or “pricking” sensation. Some report mild irritation or redness from the stimulation. You are encouraged to inform the researcher about any discomfort during stimulation and may discontinue at any point. The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

There is a risk of loss of confidentiality of your personal information as a result of participation in this study.

E. MEDICAL RECORDS AND CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help improve this ear stimulation method as a potential treatment option. This study will also help us better understand how different emotional states and thinking styles influence brain/body responses and influence learning.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $100.00 for participation in this study. Payment will be provided immediately at the end of the study in the form of a ClinCard, which is a prepaid debit card. Payment will be prorated by the hour for withdrawal before the end of the study, such that each hour will be compensated with $33.00.

Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study.

If you have mental health concerns (anxiety, depression or trauma-related stress), then alternative treatments are available. These include therapy or counseling for anxiety, depression, or stress. You also may benefit from medication. Therapy resources are available in the Institute of Psychiatry at MUSC (1-843-792-9162). If you are a veteran, these mental health resources also are available at the Ralph H. Johnson VAMC (1-843-577-5011).

In the case of a mental health emergency or crisis, call 911. If you or someone you know is suicidal or in emotional distress, call the National Suicide Prevention Hotline, 1-800-273-TALK (8255). You can get general information and locate other mental health treatment services by calling the SAMHSA Treatment Referral Helpline, 1-877-SAMHSA7 (726-4727).

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you.

K. DISCLOSURE OF RESULTS

Individual brain activity data or other bodily responses are not currently considered reliable forms of data, particularly in the research setting. No diagnoses will be made during the course of this study. As a result, no clinically relevant results will be provided to you at the end of your participation.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to

collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

N. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you

decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact **Danielle Taylor at (843) 790-4868 or taydanie@musc.edu**. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given an electronic or paper copy of this form for my own records.

Please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

_____ _____

Electronic Signature of Person Obtaining Consent Date

_____ _____

Electronic Signature of Participant Date

MUSC Medical University of South Carolina

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION (PHI)
The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, MUSC Physicians Primary Care, MUSC Health Partners, MUSC Health Alliance, MUSC Strategic Ventures, LLC, and MUSC Strategic Ventures (MSV) Health, Inc.) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect, receive, or share this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

OUR PLEDGE REGARDING YOUR HEALTH INFORMATION
MUSC is committed to protecting the privacy of health information we create and obtain about you. This Notice tells you about the ways in which we may use and disclose health information about you. It also describes your rights and certain obligations we have regarding the use and disclosure of your health information. We are required by law to: (i) make sure your health information is protected; (ii) give you this Notice describing our legal duties and privacy practices with respect to your health information; and (iii) follow the terms of the Notice that is currently in effect.

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI) –

A. The following uses do NOT require your authorization, except where required by SC law:
1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
4. Business Associates. Your medical information could be disclosed to people or companies outside our Health System who provide services. These companies typically are required to sign special confidentiality agreements before accessing your information. They are also subject to fines by the federal government if they use/disclosure your information in a way that is not allowed by law.
5. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
6. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
7. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
8. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.
9. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement or for continuum of care when in the custody of law enforcement.
10. Military and Veterans. If you are a member of the U.S. or foreign armed forces, we may release your medical information as required by military command authorities.
11. Uses and disclosures about patients who have died. We may provide medical information to coroners, medical examiners and funeral directors so they may carry out their duties.
12. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
13. Research. We may use and disclosure your medical information for research purposes. Most research projects are subject to Institutional Review Board (IRB) approval. The law allows some research to be done using your medical information without requiring your written approval.
14. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.
15. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.
16. Marketing. We may send you information on the latest treatment, support groups, reunions, and other resources affecting your health.
17. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
18. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.
19. Disaster Relief Efforts. We may disclose your medical information to an entity assisting in disaster relief efforts so that your family can be notified about your condition.
Note: incidental uses and disclosures of PHI sometimes occur and are not considered to be a violation of your rights. Incidental uses or disclosures are by-products of otherwise permitted uses or disclosures which are limited in nature and cannot be reasonably prevented.

B. You may object to the following uses of PHI:
1. Inpatient hospital directories. Unless you tell us not to, we may include your name, location, general condition and religious affiliation in our patient directory so your family, friends and clergy can visit you and know how you are doing.

2. Information shared with family, friends or others. Unless you tell us not to, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:
You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation.
1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Mental Health Records unless permitted under an exception in section A.
3. Substance Use Disorder Treatment records unless permitted under an exception in section A.
4. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:
A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**
B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI and/or appointment reminders in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.
C. The Right to See and Get Copies of Your PHI. You have the right to inspect and/or receive a copy (an electronic or paper copy) of your medical and billing records or any other of our records used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a cost-based fee. MUSC will act on a request for access or provide a copy usually within 30 days of receipt of the request. We may deny your request in limited circumstances. If you are denied access to your records, you may request that the denial be reviewed by a licensed health care professional. Additionally, we may use and disclose information through our secure patient portal which may allow you to view and communicate with certain health care providers in a secure manner. For more information see our https://mychart.musc.edu/mychart/
D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.
E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record. Notification will be provided within 60 days.
F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 349 / Charleston, SC 29425. The phone number is (843) 792-3881.
G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.
H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers, belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the U.S. Dept. of Health and Human Services, Office for Civil Rights. The address will be provided at your request or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. The changes will apply to all existing PHI we have about you.. This Notice will always contain the effective date and may be reviewed at http://academicdepartments.musc.edu/musc/about/compliance/privacy.html

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003 and was last revised on August 2018.