VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Katherine S. Aboud
Study Title: Noninvasive brain stimulation to enhance reading comprehension ability
Institution/Hospital: Vanderbilt University Department of Special Education
Revision Date: 05.15..23

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

The purpose of the study is to find ways to improve reading comprehension. We will use brain stimulation on the scalp. This stimulation is called high-definition transcranial alternating current stimulation (HD-tACS). We will also use paper/pencil tests to look at how stimulation affects reading comprehension. We will also use brain imaging to examine brain patterns of reading comprehension.

You will participate in 3 to 4 separate study visits. During each visit, you will complete some combination of brain imaging procedures (magnetic resonance imaging and electroencephalography; MRI and EEG), tests of cognitive ability, and/or brain stimulation. Each study visit will take between 2-5 hours, depending on procedures to be completed during each visit.

Potential risks of participation include: 1) discomfort from wearing an elastic cap or earplugs during EEG; 2) heating or dislodging of metal in the body during MRI; and 3) temporary dizziness, tingling, headache, or flashes in your vision during brain stimulation procedures. You will not receive any direct benefits from being in this study. Your participation may help researchers find a way to improve reading comprehension.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are an adult ages 18-40 years, you are right-handed, and you are a native English speaker.

You do not have to be in this research study. If you choose to not be in the study, your choice will not change your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something

new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Procedures to be followed and approximate duration of the study:

The study will be completed in 3 to 4 days and testing will take approximately 10-14 hours to complete across all study visits. If you decided to participate in this study, this is what will take place:

- You will fill out some questionnaires that will ask about things like your hand preference and occupational/educational background.
- You will come to the Neural Enhancement of Learning Lab at Vanderbilt University.
- The study team may ask you some questions about your health and background.
- You may be given several standardized tests that focus on reading skills, and skills that support reading (e.g., memory). These tests will be audio recorded for scoring purposes.
- You may be given a brief training in reading comprehension. Passages may contain medical facts that might be distressing. An example would be blood loss from a wound, other bodily processes, or references to loss of life.
- You may be asked to complete brain imaging measures (MRI/fMRI and EEG, both described below).
- You may be asked to complete two sessions of brain stimulation on the scalp. The stimulation is called high-definition transcranial alternating current stimulation (HD-tACS; described below).
- After each brain imaging and stimulation session, you may be asked questions about the session both in person, and post-session (approximately 1 week later).

The **MRI/fMRI** scan will take about 1 hour. An MRI/fMRI scan is taken in a large machine that is shaped like a tunnel. This scan does not use x-rays. Instead, they use a strong magnet and radio waves, like those used in an AM/FM radio to make pictures of your body. You may not be able to have this scan if you have a device in your body, such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear (inner ear) implants. Also, you may not be able to have this scan if you have iron-based tattoos or pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye).

Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body when you are getting the scan. Also, metal can sometimes cause poor pictures if it is close to the part of the body being scanned. For these reasons, you will be asked to remove these objects before going into the room for the scan.

You will hear "hammering", clicking, or squealing noises during the scan. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them. During the scan, the MRI/fMRI staff is able to hear and talk to you. You will also be able to hear the staff. They will be talking to you during your scan and may ask you to hold your breath, not move, or other simple tasks. You may be asked to lie very still throughout the scan.

Throughout the scan you may be asked to look at images, watch movies, read texts, or lie with your eyes closed. In this study, the MRI/fMRI scan is for research only. But, if we see something that is not normal, you will be told and asked to consult your doctor.

If you have medical implants or devices, we may ask you to bring in medical records that confirm that the implant/device is safe to go inside the MRI. An electronic record of this information will be stored in a secure online server, and any physical copies you provide will be shredded through secure University shredding options.

For the **EEG** portion of the study, you will be seated in a comfortable chair in a sound-treated room. Throughout the testing procedure, you will look at images or read texts on a computer monitor or screen. Sensors will be placed on your head that will record brain-related electrical activity from your scalp using a device called an EEG (electroencephalogram). You may be asked to wear a cap with sensors attached to it.

To get good contact between the sensors and your scalp we may use an alcohol pad and/or mild exfoliating gel to remove surface oils and dirt. A small amount of conductive gel or paste may either be placed on the sensor, or the cap may be soaked in a saline solution prior to the experiment. This conductive gel/paste, or the saline solution, will get in your hair but can be washed out. If necessary, the sensor may be fixed in place using adhesive tape. The electrical activity that we record is generated directly by your body.

EEG devices have been in regular medical and scientific use for five decades with no reported problems. Most people do not experience any discomfort from the procedure. However, some participants occasionally report slight discomfort from the gel/paste tangling their hair or irritating their scalp, from wearing a tight-fitting elastic cap, or from wearing an insert earphone for an extended period. Please keep in mind that if you become uncomfortable at any time during the study, you are free to discontinue participating.

For the **stimulation (HD-tACS)** portion of the study, you may come in for 1 to 2 separate visits no less than 1 week apart. Stimulation may be performed in-scanner during the fMRI and/or during the EEG, using the approved HD-tACS system, and it's built-in fully MRI- and EEG-compatible features, respectively.

Throughout the testing procedure, you will be seated or laying in a comfortable position and look at images or read texts on a computer monitor or screen. You will be randomly assigned to either receive real stimulation or fake (sham) stimulation. You have a 50% chance of being assigned to one of the two groups (like the flip of a coin).

For both real and fake stimulation, sensors are placed on the head and deliver a harmless, passive current through your scalp. You will not be able to tell whether you are receiving real stimulation or sham stimulation. HD-tACS is a procedure in which a device sends a small current across the scalp. These currents generate an electrical field in the brain that changes brain function. HD-tACS mechanisms are considered to result from the ability of very weak currents to make reversible changes to brain activity.

Expected costs:

There is no cost to you for taking part in this study.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

There are minimal risks associated with **paper/pencil and computerized testing**, although potential risks include boredom, fatigue, and psychological stress of test taking. This will be kept to a minimum. Breaks and encouragement will be given as needed during testing in order to minimize boredom, fatigue and psychological stress of test taking. In addition, testing may be discontinued at any time on your request. Although we will be flexible in terms of scheduling testing dates, there is a chance you may miss work. The non-medical risk in a data-gathering study is breach in your confidentiality. To protect your information, we will use a unique ID. This ID will be use instead of your name on all the information that is gathered for the study. Your paper records will be kept in a locked office.

There are no known major risks with an **MRI/fMRI** scan. But, it is possible that harmful effects could be found out in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan.

If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs. If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off during the MRI/fMRI scan. Transdermal patches slowly deliver medicines through the skin. Some patches have metal in the layer of the patch that is not in contact with the skin (the backing). You may not be able to see the metal in the backing of these patches. Patches that contain metal can overheat during an MRI/fMRI scan and cause skin burns in the immediate area of the patch. Tell the study doctor that you are using a patch and why you are using it (such as, for pain, smoking cessation, and hormones). Ask your doctor for guidance about removing and disposing of the patch before having an MRI scan and replacing it after the procedure. Tell the MRI/fMRI facility that you are using a patch. You should do this when making your appointment and during the health history questions you are asked when you arrive for your appointment.

Women of Childbearing Age: There are no known risks of having MRI/fMRI scans without contrast while pregnant. However, there may be risks that are unknown.

For the **EEG**, inconveniences include the time it takes to participate in the study, boredom and fatigue from the tasks, discomfort from wearing an elastic cap or earphones, and the possibility that you may wish to wash your hair after the study.

The risks related to **HD-tACS** include: you may see brief flashes in your vision, you may also feel dizzy or tingling. Headaches have not been noted for HD-tACS. However, other brain stimulation devices may cause a brief, mild headache. These occur in about 2% of people. You may have a stiff neck or pain in your neck

while the sensors are on your forehead and you keep your head in position. If you get a headache or feel any other discomforts during the visits, tell the researcher. You may also have minor irritation, discomfort, and redness at the electrode sites. There is a possibility of burns or electrical shocks from using the device. You may stop the study at any time.

If some of these side effects persist beyond what is expected, you may be asked to see your PCP or go to a walk-in clinic" and could be responsible for seeking care for minor side effects.

Unforeseeable risks:

Because this treatment (HD-tACS) is investigational, meaning non-FDA approved, there may be unknown or unforeseeable risks associated with participation.

Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator [with Sponsor input] that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt [or the Sponsor] to pay for the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

Good effects that might result from this study:

a) **The benefits to science and humankind that <u>might</u> result from this study.** The information gained from this study may help researchers find a way to enhance learning new information when people read.

b) **The benefits you might get from being in this study.** You will not receive any direct benefit from this study.

Study Results:

Individual study results are not shared with research participants.

Alternative treatments available:

You can choose not to take part in this study. If you are receiving care at Vanderbilt, you will still receive the same care even if you choose not to take part.

Compensation for participation:

The total compensation for each visit will be up to $150. All payments will be issued by mail or electronically after completion of the individual visit requirements. The payment breakdown is: $25 for participation in behavioral testing, $75 for participation in MRI imaging, and $50 for participation in EEG imaging. Any additional behavioral assessments/experimental measures may be compensated at a rate of $10/hr. Additional fMRI/EEG or stimulation measures may be compensated at a rate of $25/hr. If sessions are terminated early for any reason, compensation will cover the study session up to and including the point of termination. All study payments will be issued electronically or by mail.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Circumstances under which the Principal Investigator may withdraw you from study participation:

The PI may withdraw you from the study if they feel that it is in your best interest. As required by U.S. Law, a description of this clinical trial will be available on:

https://clinicaltrials.gov/ct2/show/study/NCT05523505?term=aboud&draw=2&rank=2

This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

What happens if you choose to withdraw from study participation?

You may discontinue the study at any time.

Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact Dr. Katherine Aboud at: (703) 851-2588.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at: (615) 322-2918, or toll free at: (866) 224-8273.

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Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. All data and medical information obtained will be considered privileged and confidential. At study entry, you will be assigned an identifying code number, and names and ID numbers are stored separately. Physical data, including written data and medical records, will be kept in locked filing cabinets. Electronic data is stored and/or processed on HIPAA-compliant, password-protected secure servers, and data are accessible only to research staff members.

As part of the study, the study team may share your de-identified study data with other researchers and with the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board and National Institutes of Health. Anonymized data may be shared with open-source data platforms in order to support best practices in research. The study results will be kept in your research record for at least five years after the study is finished.

Unless told otherwise, your consent to use or share your study data does not expire. If you change your mind, we ask that you contact Dr. Katherine Aboud in writing and let her know that you withdraw your consent. Her email address is: katherine.aboud@vanderbilt.edu. At that time, we will stop getting any more data about you. But, the data we collected before you withdrew your consent may still be used for reporting and research quality. You will get a copy of this form for your records.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

May we contact you in the future about other research conducted by the Neural Enhancement of Learning Lab? **Circle:**

Yes or **No**

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

By signing below, I confirm that I have read this informed consent document, and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate in this research study.

Date Signature of participant/volunteer

Consent obtained by:

Date Signature

Printed Name and Title