# Document Coversheet

Study Title: The Effects of Transcranial Direct Current Stimulation on Fear Extinction Learning and Memory Processes

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**KEY INFORMATION FOR**
**ENHANCEMENT OF EMOTIONAL LEARNING WITH TRANSCRANIAL DIRECT CURRENT STIMULATION**

We are asking you to choose whether or not to volunteer for a study designed to test whether transcranial direct current stimulation (tDCS) augments psychological and neurobiological processes related to the treatment of anxiety. Please understand that this is not a treatment study. tDCS is a form of non-invasive brain stimulation that involves placing electrodes on your scalp and passing a weak electrical current between the electrodes. A small amount of this electricity reaches the brain and can modulate brain activity. tDCS is safe and minimal risk for most individuals; side effects are minimal in most circumstances. We are asking you because you are a psychiatrically-healthy volunteer. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

**WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?**

By doing this study we hope to learn more about how tDCS effects brain and behavioral processes that are important to the treatment of anxiety. All interested persons must first complete an in-person screening visit to determine eligibility. If eligible, then your participation in this study will consist of 3 appointments over the course of 3 consecutive days. Each appointment will last up to 2 hours and the total amount of time you will be asked to volunteer is up to 9 hours (including screening).

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**

You will not get any personal benefit from taking part in this study. If you chose to take part in this study, you might help the researchers gain information that could help improve the understanding and efficacy of treatments for anxiety disorders.

For a complete description of benefits, refer to the Detailed Consent.

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**

The experiments performed in this study are not greater than minimal risk. We do not compensate for the screening visit. This study will be demanding of your time. Study visits must be scheduled on 3 consecutive days at approximately the same time each day. You may not want to volunteer if you are unable to undergo an MRI. The MRI will require you to lay awake and still in a small chamber for up to 60 minutes. You may receive highly annoying, but not painful finger shocks during the picture viewing task. You will also receive real or placebo tDCS on day 2. tDCS is safe for most individuals but can be uncomfortable at the site of stimulation. (e.g., itching or mild burning sensations on the forehead are common).

For a complete description of risks, refer to the Detailed Consent.

**DO YOU HAVE TO TAKE PART IN THE STUDY?**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s).

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?**

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Thomas Adams, PhD of the University of Kentucky, Department of Psychology at tgad224@uky.edu or 859-257-6481. If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

# DETAILED CONSENT:

## ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You may not qualify to volunteer for the study if:

- You have been recently diagnosed with a psychiatric disorder or substance abuse/dependence disorder.
- You are pregnant or lactating
- You are unable to undergo MRI
- You suffer from claustrophobia or feel uncomfortable in small enclosed spaces
- You have any implanted medical devices such as a pacemaker or significant metal implants in your body (for example, a metal skull plate)
- You have a history of epilepsy, seizure, stroke, significant brain injury, frequent severe headaches, or neurological diseases
- You have had an adverse reaction associated with brain stimulation.

## WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at the UK Medical Center in the Magnetic Resonance Imaging and Spectroscopy Center (MRISC). You will need to come up to four times during the study. Each of those visits will take about 1-2 hours. The total amount of time you will be asked to volunteer for this study is up to 9 hours inclusive of the eligibility screening and the three consecutive experimental sessions.

## WHAT WILL YOU BE ASKED TO DO?

### Screening

If you decide to participate in the study, you will be visiting the UK MRISC as part of your study procedures. If you agree to take part in the study, you may be asked to complete one or more screening visits remotely, via Zoom. This screening period will allow us to rule out most psychiatric diagnoses and to evaluate any reasons that participating in this study might not be the appropriate choice for you. The evaluation period of the study will include up to a two hour-long interview by a member of the research team and a separate standardized structured interview with rating assessments by research staff. You will also be asked to complete some self-report measures.

During these evaluations, you may be asked to complete the following questionnaires:

- *MINI International Neuropsychiatric Interview:* Involves a 20-30 minute interview to establish psychiatric diagnoses.
- *tDCS Contraindications Checklist*: a brief interview to determine if you are at an increased risk for tDCS side effects.
- *MRI Screening Checklist:* Is a brief interview to determine if you are at increased risk of MRI side effects.
- *Patient Health Questionnaire (PHQ-9):* a brief self-report scale about your health and any symptoms of depression.
- *Generalized Anxiety Disorder Questionnaire (GAD-7*): a brief self-report scale about symptoms of anxiety.
- *Mini-Mental State Examination:* Is a short interview to determine your current cognitive functioning and to assess if you have any cognitive impairment.

We may collect urine samples to screen for drugs. All women of childbearing age will be questioned about the possibility of pregnancy and may have a pregnancy test. If a pregnancy test result is positive, or if pregnancy is suspected, you will not be able to participate in the study.

Once you have completed the screening intake, we will ask you to get a COVID-19 test prior to participating in the study. You will need to have a negative test within one week of your screening visit.

Dr. Adams or a member of the study team will schedule you for your COVID-19 test with WildHealth. There will be no cost to you or your insurance for the test. We will collect your Social Security number in order to register you for the COVID-19 test, but will not keep this information after the test is scheduled.

If you test positive for COVID-19, you will not be allowed to participate in the study.

Once you have completed the screening evaluation process, you may be invited to consider participation in the study of Transcranial Direct Current Stimulation (tDCS) and its effects on brain and behavioral processes associated with emotional learning and memory. These procedures will involve a computerized learning and memory task, neuroimaging measures such as magnetic resonance imaging (MRI), psychophysiology measures such as heart rate, electrodermal activity, and respiration, subjective ratings, and clinical assessments, and tests of cognitive functions.

The study procedures will investigate your experiences during standard practices to help us explore possible underlying psychological and brain processes, as follows:

**Computerized Emotional Learning and Memory Task**

The computerized emotional learning and memory task will involve repeated presentations of a few photos on a screen. A finger shock may or may not follow the photos. Small electrodes will be placed on two fingers to deliver the finger shock. You will select a shock intensity that you find to be highly annoying but not painful. The presentation of shock will cause some mild discomfort. You will complete the computerized learning and memory task on three consecutive days. You will also be asked to provide subjective ratings of the photos at the end of each experimental session.

**Magnetic Resonance Imaging (MRI)**

You will be asked to complete MRI scans on each of the three experimental sessions. Each MRI session will last about 60 minutes. MRI is a method to produce a high-resolution, three-dimensional structural picture of your brain. Functional MRI (fMRI), is a variant of MRI that measures changes in brain activity under changing circumstances, like when you see an image or hear a sound. Diffusion weighted imaging (DWI) is also a variant of MRI that measures the structures in your brain. These brain imaging techniques use magnetic fields and radio waves and are similar to those you might get in a hospital.

The one thing we do have to be careful of is that no metallic objects can be brought into the room where the MR scanner is located, because of the strong magnetic fields being used. You must remove all metal objects before entering the magnet room and these will be held for you until you complete the test. You must complete a MR screening checklist which checks for metal in your body because magnetic metal in your body (such as a pacemaker) may be incompatible with having an MRI scan. We ask all participants involved with the study to be scanned with a wand designed to detect metal objects. If there is any doubt as to whether you have metal in your body, such as from metal work (e.g. welding), you will not be able to participate in the study.

After completing the screening checklist and storing any metal belongings and anything that might be damaged by the magnetic field (such as credit cards) in a locker, you will lie on your back on a firm platform inside a big tube-shaped magnet. You will notice that the magnet makes a "drumming" or “knocking” noise when it is operating; this can become loud, so you will be provided with earplugs and/or headphones. A member of the research team will watch you closely throughout the study and will be available to answer any questions you may have. If at any time during the experiment you become uncomfortable, you can inform this person and the session can be paused or stopped.

**Psychophysiological Measurements.**

As part of your participation we will measure at least one of the following during the computerized learning and memory task and during all MRI brain scans. These psychophysiological measures may include: electrodermal activity (EDA), heart rate (HR), respiration.

To measure EDA, electrodes filled with isotonic paste will be placed on your hand. This will measure the electrodermal conductance of sweat glands in your palm. These glands are known to be highly sensitive to different stimuli, such as emotional responses. When physiologically arousing stimuli occur whether externally or internally, momentarily, the skin in your palm becomes a better conductor of electricity and this change can be measured. To measure HR, we will place a small photoplethysmograph (light emitter and receiver) on your index

finger. This tool allows us to non-invasively measure HR and associated indices. We may also measure HR with a chest strap and electrocardiogram (ECG) using chest electrodes. Respiration may be assessed with a chest strap that measures chest contractions. If necessary, a gender matched experimenter will assist you with placement of the chest strap(s) and chest electrodes.

### Transcranial Direct Current Stimulation (tDCS)

We utilize a common research method, **tDCS**: tDCS is a safe procedure with minimal risk. You will receive tDCS for approximately 20 minutes while you undergo the MRI. During tDCS, you will have 8 electrodes soaked with saline or gel secured to your scalp with a neoprene cap. The tDCS device will deliver a very small electrical current between the electrodes, some of which will pass through your scalp and will reach your brain. This causes small changes in the electrical activity in certain areas within your brain that can increase or decrease the chances that neurons in your brain will fire. These changes in electrical activity are, however, believed to be insufficient to cause neurons to fire by itself. Changes in brain activity from tDCS are believed to last upwards of 90 minutes after stimulation has ended. You may feel heat, itch, and/or tingling (the most common tDCS side effects) beneath the electrodes during stimulation and/or perhaps a mild headache for a short period after tDCS. These side effects tend to abate after the first 30-60 seconds of stimulation, can usually be mitigated by adjusting the electrodes or adding saline or gel, and rarely persist after stimulation has ended. You may withdraw from this study at any time if tDCS session is too uncomfortable for you.

The tDCS session you engage in may be a "sham" session (meaning you will not receive the actual procedure). To avoid influencing the results, you will not be told if a session is a sham session or not. There is no way for you to determine if you receive the actual procedure or not. Research staff will not know whether or not you receive sham stimulation.

Following the procedure, you will be asked to complete a *tDCS Side Effects Questionnaire*. This is a brief questionnaire to determine if you experienced any side effects following the application of tDCS.

### Clinical Assessments

You will be asked to complete a brief battery of self-report clinical assessments related to mood and emotion. These should take no more than 15-minutes to complete.

### Cognitive Function Tests

We will administer computerized and experimenter-administered tests of cognitive functions. These tasks assess a range of cognitive functions, including, but not limited to executive functioning (e.g., cognitive control) and intelligence. These will be standard cognitive tests and take 10 to 60 minutes to complete.

## WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The methods that we propose to use present minimal risk. The risks involved with this study include those associated with psychiatric evaluations and clinical assessments, the computerized emotional learning and memory task, MRI procedures, and tDCS.

**Psychiatric Evaluation, Clinical Assessments, and Tests of Cognitive Functions:** The major disadvantage of these procedures is the time it takes to complete them. Some of the questions asked during the psychiatric evaluation and clinical assessments may cause some emotional distress. We have asked these questions many times in the past for other studies without subject distress, so we believe you will probably find them acceptable; however, you do not have to answer any questions that you do not want to answer. You will be offered short breaks if you need them.

**Emotional Learning and Memory Task:** There will be some physical discomfort. This discomfort will be based on the intensity that you chose for the finger shock. It is intended to be highly annoying but not painful. You may choose to stop the task at any point by informing the staff.

**MRI:** MRI is a technique that uses magnetism and radio waves, not x-rays, to take pictures and measure molecules of different parts of the body. The United States Food and Drug Administration (FDA) has set guidelines for magnet strength and exposure to radio waves, and we carefully observe those guidelines. You will be watched closely throughout the MRI scans. Some people may feel uncomfortable or anxious. If this happens to you, you may ask to stop the study at any time, and we will take you out of the MRI scanner. On rare occasions, some people may feel dizzy, get an upset stomach, have a metallic taste or feel tingling sensations or muscle twitches. These sensations usually go away quickly but please tell the research staff if you have them.

There are some risks with an MRI for certain people. If you have a pacemaker or some metal objects inside your body, you may not be in this study because the strong magnets in the MRI scanner might harm you. Another risk is the possibility of metal objects being pulled into the magnet and hitting you. To lower this risk, all people involved with the study must remove all metal from their clothing and all metal objects from their pockets. We also ask all people involved with the study to be scanned with a metal detector wand.to detect metal objects. It is important to know that no metal can be brought into the magnet room at any time. Also, once you are in the magnet, the door to the room will be closed so that no one from outside accidentally goes near the magnet.

We want you to read and answer very carefully the questions on the MR screening Questionnaire. Be sure that you have read the MR screening questionnaire and be sure to tell us any information you think might be important.

**Psychophysiology:** There are no risks to you beyond the slight stickiness of the paste and adhesive being used with electrodes. You will be offered paper towels to wipe your hand after the testing is completed. You may be uncomfortable, connecting the chest strap(s) used to monitor heart rate or respiration. A gender-matched experimenter will assist you with this if needed.

**Transcranial Direct Current Stimulation (tDCS):** You may feel heat, itch, and/or tingling beneath the sponge electrode pads during stimulation or a mild headache during tDCS and for a short period after tDCS; though headaches are rare with the methods used in this study. These sensations generally go away shortly after the conclusion of the procedures. If you become uncomfortable, you should inform the research staff. You may ask to stop the study at any time if you feel the tDCS is too uncomfortable and we will stop immediately.

In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

**WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?**

We do not know if you will get any benefit from taking part in this study. However, if you take part in this study, information learned may help people with anxiety and related disorders and may contribute significantly to our understanding of this illness.

**IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**

Participating in this study will not provide you with any form of treatment. If you do not want to be in the study, there are no other choices except not to take part in the study.

**WHAT WILL IT COST YOU TO PARTICIPATE?**

You will not be responsible for the costs of any of the evaluations or tests associated with participation in this project, There will be no cost to you for the COVID-19 test at WildHealth during the screening process.

**WHO WILL SEE THE INFORMATION THAT YOU GIVE?**

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law.

We will ask for your social security number in order for you to be compensated for participation in the study, as well as to schedule you for your COVID-19 test at WildHealth. Your social security number will not be linked with your study data. If you choose not to provide your social security number, you may still participate but will not receive any payment.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. All information about you will be kept in locked offices and files or on encrypted and password-protected computers, or on secure servers. Procedures to ensure confidentiality will follow the regulations and policies of the University of Kentucky. The research team will only give this coded information to

others to carry out this research study. The link to your personal information may be kept for up to seven years past the close of the study, after which time the link will be destroyed and research data will become anonymous. The data will be kept in this anonymous form indefinitely as part of the principle investigator's records.

You should know that in some cases we may have to show your information to other people. For example, the law may require us to share your information with:

- authorities, if you report information about a child being abused; or if you pose a danger to yourself or someone else.
- If you test positive for COVID-19, your test results will be reported to the appropriate authorities.

To ensure the study is conducted properly, officials of the Food and Drug Administration, the National Institutes of Health, and the University of Kentucky may look at or copy pertinent portions of records that identify you.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

## Certificates of Confidentiality (CoC):

To help us protect your privacy, we have obtained a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH). Once granted, the researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena, unless you have consented for this use. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below:

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that is needed for auditing or program evaluation by the NIH, which is funding this project, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). They cannot report anything that would harm you or other research subjects.

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for anyone to receive information about your participation in the research, then we may not use the CoC to withhold this information.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will gather information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, date of birth, address, contact phone numbers and other information necessary to register you.

The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the study sponsor (i.e., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse or neglect
- about harm to yourself or others; and
- about you if it involves a reportable disease.

If any member of the research team is given such information, he or she will make a report to the appropriate authorities. This policy does not prevent you from releasing information about your own participation in this study.

## CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with the University of Kentucky. You will not be treated differently if you decide to stop taking part in the study. At your request, you can be referred to a clinic or doctor who can offer you treatment.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- you are significantly late to research appointments
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for administrative or scientific reasons.

## ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study in which you do not know the treatment. It is important to let the investigator know if you are in another research study. You should discuss this with the investigator before you agree to participate in another research study while you are in this study.

## WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call the principal investigator, Thomas Adams, PhD at 859-257-648 immediately.

Thomas Adams, PhD will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility or may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

## WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive up to $240 for taking part in this study; $40 for study completion of assessments and cognitive tests, $50 per experimental session, and a $50 bonus for completing all study procedures. Payments will be pro-rated as you complete each visit. Payments will be made by cash or check at the time of your visit.

With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

## WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

**WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?**

The information obtained through this study will be kept with the research team and will not be shared with you. This MRI study is for research purposes only and is not in any way a health care examination of the brain. The scans performed in the study are not designed to find abnormalities. The principal investigator, the lab, the MRI technologist, and the MRISC are not qualified to clinically interpret the MRI scans and are not responsible for providing a health care evaluation of the images. Based on his recommendation (if any), the principle investigator or consulting physician will contact you, inform you of any abnormal findings that are detected, and recommend that you seek medical advice as a precautionary measure. The decision for additional examination or treatment would lie only with you or your physician. The investigators, the MRISC, and the University of Kentucky are not responsible for any examination or treatment that you receive based on these findings. The images collected in this study are not a health care MRI exam and for that reason, they will not be made available for health care purposes.

**WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?**

The research staff would like to contact you in the future with information about participating in additional studies that may be of interest to you. If so, it will be limited to twice per year.

Do you give your permission to be contacted in the future by the principal investigator or a member of his research team regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

**WHAT ELSE DO YOU NEED TO KNOW?**

If you volunteer to take part in this study, you will be one of about 32 people to do so at the University of Kentucky.

The National Institutes of Health (NIH) is providing financial support and/or material for this study.

The information that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

A description of this clinical trial is available on ClinicalTrials.gov as required by U.S. Law. 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 website at any time.

**WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?**

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. After we remove all identifiers, the information may be used for future research or shared with other researchers without your additional informed consent.

**Possible study tasks –** Please place your initials on the lines that best match your decision on whether or not you wish to participate in the following study procedures:

**Are you willing to complete the psychiatric and eligibility screening/evaluation?**

_____ I **agree** to participate in the psychiatric and eligibility screening/evaluation

_____I **do not** agree to participate in the psychiatric and eligibility screening/evaluation

**Are you willing to also participate in the computerized emotional learning and memory task?**

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| ____ I **agree** to participate in the emotional learning and memory task<br>____I **do not** agree to participate in the tDCS procedures |

**Are you also willing to participate in the MRI scans?**

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| ____ I **agree** to participate in the MRI scans<br>____I **do not** agree to participate in the MRI scans |

**Are you also willing to participate in the psychophysiological assessments?**

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| ____ I **agree** to participate in the psychophysiological assessments<br>____I **do not** agree to participate in the psychophysiological assessments |

**Are you also willing to receive transcranial direct current stimulation (tDCS)?**

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| ____ I **agree** to participate in the tDCS procedures<br>____I **do not** agree to participate in the tDCS procedures |

**Are you also willing to participate in the clinical assessments?**

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| ____ I **agree** to participate in the clinical assessments<br>____I **do not** agree to participate in the clinical assessments |

**Are you also willing to participate in the cognitive assessments?**

| |
|---|
| ____ I **agree** to participate in the cognitive assessments<br>____I **do not** agree to participate in the cognitive assessments |

## AUTHORIZATION TO USE OR DISCLOSE YOUR INDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

**Your health information that may be accessed, used and/or released includes:**

- The results of your COVID-19 test, if performed at the CCTS outpatient clinic.
- Your medical record number, to add the results of your COVID-19 test if performed at the CCTS outpatient clinic.

**The Researchers may use and share your health information with:**

- The University of Kentucky's Institutional Review Board/Office of Research Integrity
- University of Kentucky representatives; UK Hospital
- Center for Clinical and Translational Science (CCTS)

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state law.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

Current or future healthcare at the University of Kentucky;

Current or future payments to the University of Kentucky;

Ability to enroll in any health plans or

Eligibility for benefits.

**After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:**

Send a written letter to: Thomas Adams, PhD to address to inform him of your decision.

University of Kentucky

Kastle Hall Room 105

Lexington, KY 40506

Researchers may use and release your health information **already** collected for this research study.

Your protected health information may still be used and released should you have a bad reaction (adverse event). The use and sharing of your information have no time limit.

**If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University**

**of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.**

## INFORMED CONSENT SIGNATURES

**This consent includes the following:**

- **Key Information Page**
- **Detailed Consent**

**You will receive a copy of this consent form after it has been signed.**

| | |
|---|---|
| _____ **Signature of research subject** | _____ **Date** |
| _____ **Printed name of research subject** | |
| _____ **Signature of person authorized to obtain consent** | _____ **Date** |
| _____ **Printed name of person authorized to obtain consent** | |