

**Official title: Modulating Ventral Striatal Activity and Connectivity With Transcranial Focused Ultrasound as a Putative Novel Intervention for Cocaine Use Disorder**

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**UPMC** | University of Pittsburgh  
Medical Center

*Western Psychiatric Institute and Clinic*

3811 O'Hara Street  
Pittsburgh, PA 15213

## CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

**TITLE: Modulating ventral striatal activity and connectivity with transcranial focused ultrasound as a putative novel intervention for cocaine use disorder: The MATRIX research study**

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**SOURCE OF SUPPORT:** National Institute on Drug Abuse

**Questions about the Study:** You can contact the principal investigator, Dr. Mary Phillips, if you have questions, concerns or complaints about the study at 412-383-8206.

### ***Key Information***

You are being asked to take part in a research study. Research studies include only people who choose to take part. The study team will explain the details of the study to you and will answer your questions. Take your time to make your decision to participate

This study will examine the effects of noninvasive stimulation on brain activity as measured by functional magnetic resonance imaging (fMRI) in healthy young adults. We are anticipating 52 adults (18-45 years old) will participate in 9 study visits over the course of about 6 months.

The study procedures include:

- answering questions about topics like your health history and feelings
- receiving brain stimulation from transcranial focused ultrasound (tFUS)
- taking pictures of your brain structure and function in CT (computerized tomography) and MRI scanners during rest and while doing a task
- taking urine drug and salivary and/or breath alcohol tests
- taking urine pregnancy tests in participants with child bearing potential
- pushing buttons during computer tasks

tFUS is a brief stimulation of a part of your brain called the ventral striatum with low-intensity sound waves that pass through the scalp and skull safely. At one tFUS session, you will hear and feel a similar sensation, but your brain will not be stimulated. We will not tell you which condition of tFUS that you receive on which day. The ventral striatum has not been targeted

with tFUS in humans before but that other brain regions close to the ventral striatum have been safely activated with similar doses of stimulation.

This is a first-stage pilot study. tFUS has not been approved by the FDA (except for treatment of essential tremor). tFUS studies have been completed in humans and brain regions close to the ventral striatum have been safely activated with similar doses of stimulation. However, this is the first human tFUS study specifically targeting a part of the brain called the ventral striatum, so there may be risks that are unknown at this time. As with any experimental procedure, there may be adverse events or side effects that are currently unknown and some of these unknown risks could be permanent, severe or life-threatening. If you experience any unusual sensations or complaints, the research activities will cease. A study physician will be on site during the procedures to assist with any problems that may arise

Risks and side effects related to the study procedures include those which are:

*Likely:*

- You may feel boredom and/or tiredness from the testing procedures
- The risks associated with having an MRI brain scan are minimal such being uncomfortable in the scanner. You cannot have any metal in your body because of the large magnet the MRI uses.
- You cannot be pregnant and have an MRI or CT scan.
- Mild drowsiness or inattentiveness
- Physical discomfort

*Less Likely:*

- Feeling emotional discomfort (such as anxiety)
- Headache, scalp heating, neck pain, muscle twitches, itchy/irritated skin
- Feeling anxious in the MRI scanner because it is a small space
- Mild temporary or permanent cognitive function changes such as confusion or problems paying attention

*Rare but serious:*

- Redness of skin and burns

There is more information on the risks on page 4-5.

### Benefits

You will receive no direct benefit from participating in this study. The findings may help increase knowledge of and find better ways to diagnose and treat psychiatric disorders in the future.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by US 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.

### ***What procedures will be performed for research purposes?***

Below is an overview of the study visits and procedures:

Visit 1: screening visit (answer questions to check eligibility)

Visit 2: baseline MRI scan and CT scan

Visit 3: practice tFUS

Visit 4: MRI scan and tFUS

Visit 5: next day follow up (answer questions)

Visit 6: 3 day follow up (answer questions)  
Visit 7: MRI scan and tFUS  
Visit 8: next day follow up (answer questions)  
Visit 9: 3 day follow up (answer questions)

More detailed information on each study visit and associated procedures is described below

### **Screening Visit Procedures:**

The first visit consists of procedures that are called “screening procedures” that will help us to determine if you are eligible to take part in the research study. This visit will take approximately three hours of your time. The visits will take place at UPMC buildings or remotely on UPMC Vidyo or Pitt HIPAA compliant Zoom. These are secure software platforms on the internet with a smartphone or a web camera and speaker. Remote visits will be conducted in private rooms behind closed doors and will not be recorded or saved. For this research study, the screening procedures include:

1. A structured clinical interview to establish lifetime psychiatric history, which will also include questions about your life and health, and your family history of psychiatric illness.
2. Assessment of your current mood
3. Completing questionnaires covering themes such as lifetime history of mood and personality, behavior, and family history of psychiatric disorders
4. A short reading and memory test
5. A vision test to check that you can see the pictures used in the experiment
6. A questionnaire to establish whether you are right- or left-handed
7. Inquiry about your native language
8. Physical measurement of your chest circumference to assure comfort in the scanner (if the visit is done remotely and you don't have a measuring tape or hula hoop, we will try to assess visually and measure if needed at the next visit)
9. Medical history including history of head injury, implants and any other possible metal you may have in your body, medications, and possible pregnancy
10. Questions about your typical alcohol and drug use

If during the visit there is concern, crisis services may be called at clinician/PI discretion. If you are found to have a mental health condition (e.g., untreated major depression), our clinician may recommend seeking mental health or addiction support prior to moving forward with the assessment

The psychiatric assessment and other screening questionnaires will confirm that you are eligible to participate. If you are eligible, then we will ask you to take part in the experimental procedures described in the next section. If any of the screening tests show that you are not eligible, you will receive payment for the visit, and your participation will be done.

If you do not finish Visit 1 due to not meeting eligibility criteria for a temporary reason (such as if you do not have a substance use disorder but you used a stimulant in the last month to study for a test), then the visit will be stopped and you will be scheduled for a Visit 1 Update at a future time when you will likely meet eligibility criteria. This Visit 1 Update will consist of some/all of the measures used at Visit 1.

If there is a gap of 2 months or more between your first and second visit, a Visit 1 Update will be scheduled to recheck whether you still meet eligibility criteria to participate in this research study. This visit will consist of many of the same assessments and questionnaires used at Visit 1 and may be conducted in person or remotely using Vidyo or Pitt HIPAA compliant Zoom.

## **Scan Visit Procedures**

If you qualify to take part in this research study, you will have 4 scan visits at UPMC Western Psychiatric Hospital (WPH) and the Magnetic Resonance Imaging Research Center (MRRC) at UPMC Presbyterian. Each visit will take approximately 2-5 hours. We will ask you not to wear hair products, make-up, or clothing with metal on/in it for this visit. At all scan visits, you will also be asked to provide a urine/saliva sample to test for drug/alcohol use and pregnancy (in participants with child-bearing potential) prior to entering the scanner.

### *Baseline Scan Visit*

At the first scan visit, you may have 2 different types of scans: a CT scan and an MRI scan. If you have participated in a Phillips lab study before, then you may not need to complete the MRI scan if you have useable data because we will use your MRI data from the previous study visit.

Both the MRI and CT scans are very similar and will take pictures of your brain in a tunnel like machine. The difference between a CT scan and an MRI scan is that the CT scan takes pictures of your brain with x-rays, while the MRI scan takes pictures of your brain with magnetic fields. During the scans, you will lie on a table that will move you into the tunnel for an expected duration of 30 minutes (the entire visit will take about two to three hours). You will be asked to lie still without moving during the scan. The scanner makes loud, banging sounds during the study but you will be wearing protective earplugs. You will be able to talk to and hear the replies of the scanner technician. You must lie with your head and neck inside the narrow scanner tube and some people experience claustrophobic feelings (fear of enclosed spaces) while in the scanner. If you experience this or for any reason feel that you cannot remain in the scanner, the scan can be interrupted and you will be able to rest outside of this enclosed area or stop the procedure if you choose. During the scans, you will rest and try to remain as still as possible.

Prior to entering the scanner, you will:

1. Review the experimental procedures with the investigator and ask questions that you may have about the study visit
2. Be given the opportunity to see what it is like inside a replica of the MRI machine
3. Provide a urine sample to test for pregnancy in participants with child bearing potential and drug use
4. Provide a saliva sample to test for alcohol use
5. Complete a vision test
6. Remove jewelry, body piercings, keys, and other metal objects
7. Put in earplugs and/or headphones to lessen the loud noises made by the MRI machine

You will always be able to talk with the technologist while in the scanner. You will have pauses during the scanning during which we will ask you questions about any side effects, concerns or other discomfort you might be experiencing.

We will try to schedule your MRI scan and CT scan on the same day. If we need to schedule your MRI scan and CT scan to occur on separate days, you will need to complete the urine sample to test for pregnancy in participants with child bearing potential, urine drug screen, and salivary and/or breath alcohol screen prior to each scan (in other words, you would complete these tests twice: once before the MRI scan, and once before the CT scan)

If your MRI/CT data is unusable for neuronavigation, then you will not complete the rest of the study because tFUS cannot be administered without this data. If your MRI/CT data looks like it

will usable for neuronavigation, then you will be scheduled for a practice tFUS visit. At this visit, you will see the tFUS set-up and experience how the tFUS feels while the study team personalizes the tFUS settings based on your scalp features and sense of hearing.

### *Scan-tFUS Visits*

You will complete 2 visits that involve both MRI scans and tFUS. Similar to the baseline scan, you will follow the same pre-scanner procedures as discussed above, and you'll also complete a urine/saliva sample to test for recreational drug/alcohol use at all visits that involve tFUS (including practice tFUS at Visit 3). During these visits, you will have an MRI, receive tFUS, and then have another MRI. During the MRI, you will rest and have the opportunity to play a game of chance in which you can win money for your task performance by pressing buttons during the task. You will also have periods of rest during which you will look at a fixation cross on a screen.

You will receive tFUS at each visit for approximately 10 minutes; however, at one of these visits, the tFUS stimulation may be a sham. Sham stimulation involves the researcher and participant going through the motions of the normal tFUS procedures; however, you will not actually receive stimulation. You will not know or be able to tell which session is the sham stimulation because it will look and feel like the other sessions in which you receive tFUS. The amount of tFUS you will receive will be below the recommended FDA limit (ISPTA < 720 mW/cm<sup>2</sup>) (the maximum intensity occurring in an ultrasound beam) because it has been shown to be safe and well tolerated. You are encouraged to tell the research team if anything is uncomfortable. You can also choose to stop the procedure at any time.

Your mood and cognitive abilities will be assessed before and after tFUS. Any effect is expected to be gone once effects of tFUS wear off (after 1 hour); if you are having difficulties, we will refer you to appropriate medical care.

### *Next Day and 3 Day Follow Up Visits*

The day after and 3 days after each scan-tFUS visit, you will answer questions about your physical and mental health via a Vido or Zoom video visit.

### ***What are the possible risks, side effects, and discomforts of this research study?***

Some of the risks, side effects, and discomforts of this research study were detailed in the Key Information section. Here is some additional information on the risks of participating in this study.

#### Collection and Storage of Private Health Information

- **\*Infrequent risk**
  - Breach of confidentiality

#### tFUS

- **Risks**
  - This study uses low levels of brain stimulation, which have been shown to be safe and well tolerated. In rodent studies with high levels of brain stimulation, damage to brain cells and blood vessels resulting in small amount of bleeding in the brain, cell death or damage, and the passage of harmful substances from the blood into the brain were experienced.
  - Feeling emotional discomfort (such as anxiety)
  - Headache, scalp heating, neck pain, muscle twitches, itchy/irritated skin

- Mild temporary cognitive changes such as confusion or problems paying attention
- **How We Minimize Risks**
  - The study team will monitor you for side effects throughout the course of the study
  - A physician PI and/or Co-I will be on-call at all times between visits so that emergent adverse reactions can be evaluated and treated promptly.
  - A physician investigator or medical resident will be on site at all times to supervise the administration of the stimulation

#### CT & MRI scans

- **Risks**
  - Individuals who are pregnant will not be permitted to participate
  - The space inside the CT and MRI machines are fairly limited, so some people may feel claustrophobic
  - Possible discomforts you may experience while participating in the scan include the following: You may become bored, tired, uncomfortable and/or frustrated during the scan
  - Sometimes people feel anxious even after the scan is finished.
  - Sometimes people feel lightheaded when they sit up after the scan, but this should go away quickly.
- **How We Minimize Risks**
  - You will be given a 'squeeze-ball' so that you may stop the testing if you become uncomfortable or anxious at any time
  - You will have the chance to look at this space before the test starts, but if you find the small space to be a problem during the procedures, you will inform us, and the scan will be stopped.
  - If the experiment makes you feel uncomfortable in any way, you may stop the procedures, without needing to fear any consequences. The researcher will help you leave the scanner and relax afterwards before you leave.
  - The scans in this study are done to answer research questions and are not intended to diagnose medical conditions. In the unlikely event that we detect an abnormality in your scan, the technician will refer your scans (without your name) to a specialist for further examination as soon as possible after the scan. You will be contacted by phone in a timely manner should the consulting specialist recommend further examination. You will be given an opportunity to talk with the specialist. Then you and your primary care physician (PCP) (if you agree) will then decide if you should undergo further examination. The consulting specialist will be available to answer questions that you or your PCP might have about the findings of the scan. The results of your research scans will not become part of your hospital record.

#### CT scan

- **Risks**
  - Participation in this research study involves exposure to radiation from a CT scan. The amount of radiation exposure that you will receive from this procedure is equivalent to a uniform whole body dose of 4 mSv (a "mSv" is a unit of radiation dose), which is approximately 8% of the annual radiation dose (50 mSv) permitted to radiation workers by federal regulations. There is no known

minimum level of radiation exposure that is recognized as being totally free of the risk of causing genetic defects (abnormal cells) or cancer. The risk associated with the amount of radiation exposure that you will receive from participation in this study is considered to be low when compared to everyday risks and is not likely to adversely affect you, however, the effects of radiation add up over a lifetime.

- **How We Minimize Risks**

- When deciding to enter this study, the research team asks that you think about your past and future contact with radiation. Examples of contact with radiation include x-rays taken for any reason (including dental x-rays) or radiation therapy for cancer treatment.

#### MRI scan

- **Risks**

- If you have metal in your body, we will not allow you to participate because the magnet in the MRI could move these objects.
- The risk to an unborn child from the magnet is unknown, so we will not allow you to participate if you are pregnant.
- The MRI machine is loud when turned on, and may cause some discomfort
- In rare cases, MRI can cause heating of the body, and in severe cases cause redness of skin and burns. In most of these cases, heating is caused by metal such as a bracelet, medical device, or some types of tattoos containing metal that we were unaware of.

- **How We Minimize Risks**

- The safety questionnaire is designed be sure you do not have any metal in or on your body.
- If you feel sudden warming during the scan, you will be able to tell the technologist immediately so that they can stop the scan using an intercom system that allows communication with the researcher during the scan.
- You will be given a 'squeeze-ball' so that you may stop the testing if you become uncomfortable or anxious at any time
- You must wear ear plugs

#### Study assessments

- **Risks**

- It is likely that you may feel boredom and/or tiredness as a result of clinical evaluations or assessments.
- It is less likely that that you may feel emotional discomfort as a result of clinical evaluations/assessments.

- **How We Minimize Risks**

- The researchers are trained to administer evaluations/assessments in a way that will minimize your discomfort.
- You may stop the evaluation or assessments at any time if you feel uncomfortable.

#### Drug and alcohol screen

- **Risks**

- If you use alcohol and/or illicit/recreational drugs, it will show up on the salivary, breath, and/or urine test

- **How We Minimize Risks**
  - Trained study staff administer the drug screen

#### Pregnancy screen

- **Risks**
  - If you pregnant, it will show up on the urine test
- **How We Minimize Risks**
  - Trained study staff administer the test

#### Vidyo/Zoom/phone calls

- **Risks**
  - No guarantee of confidentiality and/or privacy during the session
  - It is possible that information beyond what is collected for research purposes could be accessed by others.
  - Boredom or tiredness from the length of the call/interview.
  - Infrequent risks include emotional discomfort like feeling sadness from discussing unpleasant topics, but those feelings should go away quickly after the interview
- **How We Minimize Risks**
  - Vidyo/Zoom have security precautions in place to prevent these risks from happening, although there is never a 100% guarantee
  - We will follow strict procedures to protect your information and privacy.

#### Emails and text messages

- **Risks**
  - Email and text messages may not be encrypted or secure during their transmission or storage and it is possible they could be intercepted and used by others not associated with this study.
- **How We Minimize Risks**
  - Phone numbers and email addresses are only used for communications and are not associated with any other participant identifying information.
  - Phone numbers, text messages, and email addresses are only accessible to designated staff assigned to the specific consented research project.
  - At the end of a participant's research protocol, the phone number and email address are removed from the system's database.
  - Phone numbers and email addresses are never made available to any outside entities.

#### ***If I agree to take part in this research study, will I be told of any new risks that may be found while the study is going on?***

You will promptly be notified if, during this research study, any new information develops, which may cause you to change your mind about continuing to participate. As stated above, the personal results will not be provided to you. You may have no benefit from participating in this study, and you will receive no direct benefit.

#### ***Will my insurance provider or I be charged for the costs of procedures performed as part of this research study?***

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study

***Will I be paid if I take part in this research study?***

You will be paid for participating. The study team will discuss the payment options with you.

Complete Visit 1 (screen) = \$50

Complete Visit 1 update = \$25

Complete Visit 2 (baseline MRI and CT) = up to \$120 total (\$70 for complete CT and \$50 for complete MRI)

Complete Visit 3 (practice tFUS) = \$70

Complete Visit 4 (scan-tFUS) = \$185

Complete Visit 5 (next day follow up) = \$30

Complete Visit 6 (3 day follow up) = \$30

Complete Visit 7 (scan-tFUS)= \$210

Complete Visit 8 (next day follow up) = \$30

Complete Visit 9 (3 day follow up) = \$30

Total compensation if you complete all 9 visits=\$780

At each MRI visit, there is the potential to be paid an additional money related to responding quickly during the game played in the scanner. (There is no potential to lose money)

For an incomplete visit 1, you will receive \$25. For an incomplete/partial MRI scan visit due to claustrophobia, positive pregnancy test, etc., you will receive \$10; if due to positive drug or alcohol test, you will not be compensated. If we do not complete the visit because of drug or alcohol test, there will be no reimbursement. If we do not complete a visit due to the fault of the study (for example, if the scanner is not working), then you will receive the full amount of compensation for that study visit.

If we ask you to repeat a study visit, your compensation will be the same amount as outlined above. For example, if you are at MATRIX Visit 1 and the computer freezes, you may not be able to complete the visit. You would be paid \$50 and scheduled to complete a repeat MATRIX Visit 1. The compensation for the repeat Visit 1 would be the same as the Visit 1 that you completed - \$50.

Parking Lot or traveling costs: Bus fare or parking lot costs will be paid by the study. Parking fines are your responsibility. Other travel related costs are not reimbursed.

All compensation is taxable income to the participant regardless of the amount. If a participant receives \$2000 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding'; thus, you would only receive 76% of the expected payment.

***Who will pay if I am injured as a result of taking part in this study?***

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your

research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

***Will this research study involve the use or disclosure of my identifiable medical information?***

If you are a current or past patient or research subject at WPH, this research study will not directly result in identifiable information that will be placed into your medical records. If you so choose and sign a release, we will provide information to providers you indicate. If you have never been a patient at WPH, no medical record will be created.

We are also requesting your authorization or permission to review your medical records. We will obtain the following information: psychiatric diagnosis and illness history (including most current mood states/episodes), medications, and treatment progress. This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and address billing and operational issues.

We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.

This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

***Confidentiality - Who will know about my participation in this research study?***

Any information about you that we collect from this research study will be kept as confidential (private) as possible. All records about you will be stored in locked offices and locked filing cabinets. Your identity on data records will be shown only by a case number, rather than by your name, and the information linking these numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

In addition to the investigators listed and their research staff, the following individuals may have access to your information related to your participation in this research study:

- Authorized representatives of the study sponsor, and the University of Pittsburgh Office of Research Protections may review your identifiable research information for purposes of monitoring the conduct of this research study.

- If investigators learn that you, or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable information (which may include your identifiable medical record information) for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (such as laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal hospital operations (i.e. quality assurance).
- Information collected from this study may be shared with other investigators and/or the study sponsor; however, this information will be shared in a de-identified manner (i.e., without identifiers).
- The study sponsor, National Institute of Health, may have access to the research record.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

Research records will be maintained for at least 7 years following final reporting or publication of a project.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings; if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

De-identified data from this study will be available for access by the research community via NIH Data Archive (NDA).

***Is my participation in this research study voluntary?***

Your participation in this research study is completely voluntary and you may withdraw your consent for participation, at any time. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh or medical care at UPMC.

Your doctor may be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who has nothing to do with this research study. You are not under any obligation to participate in any research study offered by your doctor.

You may withdraw your consent for participation in this research study at any time. Any identifiable research or medical information recorded for, or resulting from, your participation in this research study before the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated letter of your decision, sent to the principal investigator of this research study, at the address listed on the first page of this form.

***If I agree to take part in this study, can I be removed from the study without my consent?***

It is possible that you may be removed from the research study by the researchers if you:

- have a chronic medical condition
- have a positive drug or alcohol screens
- sustain a head injury
- have metal in your body; are claustrophobic; you are pregnant.
- no longer meet criteria for the study
- exhibit overt, aggressive behavior
- are dishonest in reporting, actively threatening, or do not follow study procedures
- have difficulty with neuronavigation and/or the MRI/CT data is unusable for neuronavigation

Finally, data collected on you may be removed from this research if, for instance, you move too much during the neuroimaging tasks. If you are removed from participation in this study at any point, all useable data previously collected will be kept without identifiers.

**VOLUNTARY CONSENT**

All of the above has been explained to me and all of my current questions have been answered. I understand that the researchers are happy for me to ask questions about anything to do with this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation.

By signing this form, I consent to participate in this research study and provide authorization to use and share my medical records. A copy of this consent form will be given to me.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

**CERTIFICATION of INFORMED CONSENT**

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

\_\_\_\_\_  
Role in Study

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

**VOLUNTARY CONSENT (ELECTRONIC SIGNATURE VIA Pitt Redcap)**

All of the above has been explained to me and all of my current questions have been answered. I understand that the researchers are happy for me to ask questions about anything to do with this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

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By signing this form, I consent to participate in this research study and provide authorization to use and share my medical records. A copy of this consent form will be given to me at my email address: \_\_\_\_\_

Full name \_\_\_\_\_

Date of birth \_\_\_\_/\_\_\_\_/\_\_\_\_

Name of high school \_\_\_\_\_