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: Elucidating neural mechanisms of hypo/mania using theta burst stimulation

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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 aims to examine the effects of noninvasive stimulation on brain activity as measured by functional magnetic resonance imaging (fMRI) in participants with and without Bipolar I Disorder. An MRI scan produces images similar to x-rays but it uses a large magnet instead of radiation. We are anticipating 284 young adults (18-35 years old) who meet inclusion criteria will participate in 5 study visits over the course of about 6 months.

The study procedures include answering questions about topics like your health history and feelings, taking pictures of your brain structure using MRI, and taking drug and pregnancy tests. The following 3 visits also involve pushing buttons during computer tasks and stimulating your brain using continuous theta burst stimulation (cTBS).

cTBS is a brief stimulation of a part of your brain with a magnetic field that passes through the scalp and skull safely. Each time you get cTBS there will be slight differences, such as scalp location, which we find using your brain images from the 2nd visit. At one session, you will hear and feel a similar sensation, but your brain will not be stimulated. We will not tell you which condition of cTBS that you receive on which day.

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

Likely:

--You may feel boredom and/or tiredness.

--The risks associated with having an MRI brain scan are minimal. Although there are no known risks from exposure to the magnetic field used for these tests, if you have metallic objects in your body, we will not allow you to take part in the study because the magnetic field in the

scanner could cause these objects to move. It is unknown if there is risk to an unborn child from the magnet, therefore, we will not allow you to take part in the study if you are pregnant.
-- Mild drowsiness or inattentiveness.
--Physical discomfort

Less Likely:
--Feeling emotional discomfort
-- Headache, nausea, fainting/passing out, and/or sudden changes in blood pressure
--Mild temporary in your thinking such as confusion

Rare but serious:
-- Seizure
--Redness of skin and burns.

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.

What procedures will be performed for research purposes?
If you decide to continue to take part in this research study, you will be asked to complete the following procedures:

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. It will take place at UPMC buildings or remotely. We will use a secure videoconferencing app, either Pitt Zoom or UPMC Vidyo, for making video calls. This requires an internet connection and a smartphone or computer with 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
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. Alcohol and drug use

The psychiatric assessment and other screening questionnaires will confirm whether you meet all the criteria for either (1) young adults without bipolar disorder or (2) young adults with bipolar disorder. If (after screening) you are considered to not have met full criteria for one of these two groups, your participation in this study will end. If you are eligible you will be asked to take part in the experimental procedures described in the next section.

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 3 months or more between your first visit and a cTBS 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.

Baseline MRI Procedures
This visit will take place at UPMC Western Psychiatric Hospital (WPH) and Magnetic Resonance Imaging Research Center (MRRC). You will be asked not to wear hair products, make-up, or clothing with metal on/in it for this visit.

At this visit, you will play a card game task and undergo an MRI scan, which will take pictures of your brain. The MRI magnet is a large tunnel-like machine; you will lie on a table that will move you into the tunnel for an expected duration of 30 minutes on this visit (the entire visit will take about one hour). 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 MRI 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.

While you are in the scanner, you will just rest and lie still. 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/saliva sample to test for pregnancy and recreational drug/alcohol use
4. Remove jewelry, body piercings, keys, and other metal objects
5. Put in earplugs and/or headphones to lessen the loud noises made by the MRI machine
6. Be asked if you have used substances with seizure risk (such as stimulants) in the past month.

You will always be able to talk with the technologist while in the scanner. You will have pauses during the scanning during which you will be asked questions about any side effects, concerns or other discomfort you might be experiencing. If you need to leave the scanner, you can resume scanning if the break is within the duration of the effect of TMS (20 mins). If a longer break is needed, the effect of TMS will have worn off and thus the scan will not be resumed.

You will also experience cTBS (continuous theta burst transcranial magnetic stimulation) at this visit. cTBS involves very brief, noninvasive stimulation of a brain area. It is FDA-approved as a treatment for psychological conditions including depression; however, this device is not

approved for the treatment of adults with Bipolar Disorder I or for use in healthy adults. This research study is using the cTBS off label in all participants (those with and without Bipolar Disorder I) to examine research questions. The study staff will be available to talk to you before you start the procedure and will give you a chance to see the device that will be used and to ask any questions that you have before beginning the cTBS process. The staff will also be standing by while you are receiving cTBS, and you should tell the research team if anything is uncomfortable. You can also choose to stop the procedure at any time.

Experimental Procedures:
If you qualify to take part in this research study, you will have 3 cTBS visits at UPMC WPH and MRRC. Each visit will take approximately 2-3 hours. We will try to schedule each visit to be about 2-3 days apart over a 2-week period. You will be asked not to wear hair products, make-up, or clothing with metal on/in it for these visits.

Before each visit, you will:

1. Review the experimental procedures with the investigator and ask questions that you may have about the study visit
2. Practice the tasks that you will complete in the scanner on a computer if needed
3. Provide a urine/saliva sample to test for drugs, alcohol, and pregnancy
4. Remove jewelry, body piercings, keys, and other metal objects
5. Put in earplugs and/or headphones to lessen the loud noises made by the MRI machine
6. Be asked if you have used substances with seizure risk (such as stimulants) in the past month.

You will receive cTBS at each visit; however, at one of these visits, the stimulation will be a sham. Sham stimulation involves the researcher and participant going through the motions of the normal cTBS procedures; however, the stimulation that you receive will be so low that it will not influence your brain activity. 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 cTBS. Similar to the baseline MRI scan visit, tell the research team if anything is uncomfortable. You can also choose to stop the procedure at any time.

At each visit, you will answer questionnaires and be scanned before and after receiving cTBS. While in the scanner you will perform tasks enabling us to observe and record your brain structure and activity. One of these tasks may provide the opportunity to play a game of chance in which you can win money for your task performance. In some cases, you will be asked to press a button during the task; other times you will rest quietly.

Similar to the baseline MRI, you will lie on a table that will move into the MRI tunnel. You will be asked to lie still without moving during the scan. 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 terminate the procedure & rest outside of the scanner. You will always be able to talk with the technologist while in the scanner and will have pauses during the scanning during which you will be asked questions about any side effects, concerns or other discomfort you might be experiencing.

Your ability to talk will be assessed before each pre cTBS scan and immediately after each post cTBS scan. Any effect is expected to be gone once effects of cTBS wear off (after 1 hour); if you are having difficulties talking, we will reassess your ability to talk 2 hours later.

We will ask if you feel suicidal or aggressive after each study visit. If you experience large and/or sustained increases in emotions and/or new/potentially harmful symptoms, you will be immediately referred to psychiatric services for assessment and leave the study if you no longer meet inclusion criteria.

If you are experiencing depressive symptoms for 2 consecutive weeks during the course of the study, we will schedule an extra screen visit to further assess your symptoms before your next scan visit. This extra screen visit can occur remotely or in person and will take no longer than 30 minutes.

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. This section will review these risks, side effects, and discomforts again, as well as provide information on other possible risks, side effects, and discomforts of this research study.

Likely:
--You may feel boredom and/or tiredness as a result of clinical evaluations or assessments.
-- Mild drowsiness or inattentiveness. We recommend taking the bus or walking to the visit rather than driving. You will be refunded accordingly.
--Physical discomfort (pain, muscle contractions) is a risk during administration of cTBS. Subjective pain reports in a prior study using nearly identical procedures dissipated within the first 15-30 sec, and no participant requested to stop. The total time that stimulation will be given at each visit is about 10 min. You may choose to discontinue at any time without penalty.
--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.
--Identification of your use of illicit/recreational drugs on the urine test

Less Likely:
--Feeling emotional discomfort as a result of clinical evaluations/assessments. 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.
--Minimal-mild post-cTBS discomfort (e.g., TMS-associated headache including migraine/migraine-related symptoms, muscle discomfort that (rarely but possibly) endures beyond the day of the stimulation, nausea)
--Temporary mild effects from cTBS on certain aspects of cognition, lasting approximately 60 min maximum, and fully resolving prior to the completion of the study visit.

Rare but serious:
--Very small risk of seizure (less than one percent), with only one such instance observed in over 1000 participants completing the current form of cTBS in research settings.
-- In rare cases, fMRI 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. The safety questionnaire is designed to avoid these situations. If you feel sudden warming during the scan you will be able to tell the technologist immediately so that they can stop the scan.

Now we will review other information related to risks, side effects, and discomforts that were not detailed in the key information section.

The risks of the cTBS procedures in this research study involve almost exclusively minimal-mild adverse events. cTBS is currently under investigation as a potential treatment for various neurological and psychiatric disorders and has been approved for the treatment of depression by the FDA in 2008. cTBS has also been used in research studies. In this study, TMS will be used in compliance with the safety guidelines recommended by the International Workshop on the safety of repetitive Transcranial Magnetic Stimulation, which were reviewed and updated in 2008.

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. The MRI machine is loud when turned on, and may cause some discomfort so you must wear ear plugs. There is an intercom system that allows communication with the researcher during the scan. You will also be given a 'squeeze-ball' so that you may stop the testing if you become uncomfortable or anxious at any time. The space inside the MRI machine is fairly limited, so some people may feel claustrophobic. 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. Sometimes people feel anxious even after the scan is finished. If this happens the researcher will help you to calm down. Sometimes people feel lightheaded when they sit up after the scan, but this should go away quickly. In these events, or 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.

We will be able to view images of your brain during the scanning session and there could be a slight possibility that we detect something unusual on your MRI scans. The MRI 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 immediately 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 MRI scan will not become part of your hospital record.

The risks associated with using Vidyo/Zoom include no guarantee of confidentiality (privacy) during Internet communication procedures and the possibility of additional information beyond that collected for research purposes being captured and used by others not associated with this study. However, Vidyo/Zoom has security precautions in place to prevent this from happening Please be aware that even with all procedures in place to prevent it, there is still a risk of breach of confidentiality. We will follow strict procedures for record keeping in order to maintain information that is related to you as confidential (private) as possible.

Use of text messaging or email for study compensation and reimbursement: 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. Emails may not be encrypted

during transmission or storage and may be intercepted and used by others not associated with this study.

The risks sections includes descriptions of possible known side effects you may experience from the stimulation. If you experience more severe symptoms that do not resolve by the end of the visit, the study staff will follow up with you via email or phone after your visit, depending on the symptom and severity. We want to check how you are doing and that the symptom has resolved and ask further follow-up questions. We may contact you for up to 6 months after the visit when you experienced symptoms

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 Screening Visit/Visit 1 Update = $35
Complete MRI Baseline Visit = $80

If you do not complete the screening visit, you will receive $25. For an incomplete/partial MRI baseline 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 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.

Complete cTBS Visit 1 = $100
Complete cTBS Visit 2 = $130
Complete cTBS Visit 3 = $170
Bonus for completing all study visits = $50
Extra MDD screen visit (as needed) = $15

In addition, there is the potential to be paid extra money from winnings related to the outcome of games of chance played in the scanner.

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 cTBS Visit 1 and the computer freezes, you may not be able to complete the visit. You would be paid $100 and scheduled to complete a repeat cTBS Visit 1. The compensation for the repeat cTBS Visit 1 would be the same as the ctBS Visit 1 that you completed - $100.

If you do not complete the questionnaires or if you decide not to complete the scan (e.g., claustrophobia) you will receive $10. If we do not complete the scan because of the presence of substances in the system, there will be no reimbursement.

Parking Lot or traveling costs: Costs for arrangements made by study personnel (eg: cab) related to your participation, will be paid for by the study. Bus fare or parking lot costs will also be paid by the study. Parking fines are not included. Other travel related costs are not reimbursed, however, if you travel more than 50 miles, you will be given an extra $100 to accommodate your increased travel expenses related to participating in this study. If an appointment runs unusually long (>4 hours), a meal ticket is provided for use at UPMC cafeterias.

All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 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 you do receive a bill for copayment or coinsurance for this emergency treatment, please contact the study team and they will assume responsibility for the co-payment or co-insurance from study fundsIf 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.

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).

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

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, federal regulatory agencies, 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; however, this information will be shared in a de-identified manner (i.e., without identifiers).

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.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

National Data Archive

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many National Institute of Mental Health (NIMH) studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing

your deidentified study data helps researchers learn new and important things about mental health and substance use more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and substance use. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

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. You can search this website at any time. At most, the website will include a summary of the results. You will not be notified of any individual research results.

HIPAA Authorization for Disclosure of Protected Health Information (PHI)
As part of this research study, we are requesting your authorization or permission to review your medical records to determine eligibility. This authorization is valid for an indefinite period of time. We will obtain the following information: your diagnosis, medications, and medical conditions. No information from research procedures will be placed into your medical records.

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 study sponsor, federal regulatory agencies, and 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 addressing billing and operational issues.

We will 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.

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 that point will continue to be used by the research team.

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.

If you are a patient participant, 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, at any point, you meet exclusion criteria (e.g., you have a chronic medical condition; your drug or alcohol screens are positive.) You may be removed from the research study because you have certain conditions (e.g.: you sustain a head injury; have metal in your body; are claustrophobic; you are pregnant.) You may also be removed from this study if you do not meet, or you no longer meet, the inclusion criteria (e.g..: you no longer meet criteria for the study group you were assigned to; your present state makes your participation unhealthy for you such as you being too anxious, depressed, etc.) Also, there are instances where you could be removed from the study due to your own actions, whether overt, aggressive, or passive in terms of study participation or with study staff, including being dishonest in reporting, actively threatening, or non-compliant with study procedures. 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.

Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. 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 WebDataXpress)
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.

Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me at my email address: _____

Full name _____

Date of birth ___/___/_____

Name of high school _____