Official Title: Theta Burst Transcranial Magnetic Stimulation of Fronto-parietal Networks: Modulation by Mental State

NCT04010461

Todays date = 5/16/2022

IRB approved consent date= 12/13/2021

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Theta burst transcranial magnetic stimulation of fronto-parietal networks: Modulation by mental state
Company or agency sponsoring the study: National Institutes of Mental Health (NIMH)

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Stephan F. Taylor, MD, Department of Psychiatry, University of Michigan
Study Coordinator: Laura M. Stchur, LMSW, Department of Psychiatry, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. Taking part in this study is completely voluntary. This form contains information that will help you decide whether to take part. All of this information is important, but here are some especially important points to keep in mind:

- Participation is completely voluntary. If you decide to participate, you are free to leave at any time.
  - If you are a patient at UM, your decision will not affect your care.
- The purpose of this study is to improve our understanding of the way a particular type of Transcranial Magnetic Stimulation (TMS) – known as theta burst stimulation or TBS – affects the brain.
  - To do this, remote video and in-person assessment study visit(s) will be scheduled to see if you are eligible to participate. Psychological assessments and cognitive measures, as well as functional Magnetic Resonance Imaging (fMRI) scans, will be completed after administration of TMS. This will take place over a series of 5-6 visits.
- There may be no benefit to individuals participating in this study, but we hope the information we gather will help us gain a better understanding of TMS.
- The use of TMS is not approved by the FDA in healthy subjects and is experimental.
- The risks associated with this study are outlined in more detail in Section 5.1 but some are briefly described below:
  - Some of the interviews may involve revealing sensitive information. We have protocols in place in protect your private information (Section 9.1).
  - The enclosed environment of the fMRI causes some individuals anxiety. Individuals need to tolerate this space well to participate.
  - TMS can cause some localized pain on your scalp near the stimulation site. The procedure can be discontinued if the stimulation is too painful.
  - fMRI can be dangerous for certain people (e.g., those with implants in their body, or those who have had bodily injuries from metal),
  - TMS can be dangerous for people who have a history of seizures.

Please take time to review this form carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study,

you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The goal of this research study is to further our understanding of how TMS affects brain activity. TMS is a useful tool that can be used to activate, or stimulate, parts of the brain temporarily. TMS can provide evidence that a given brain region is necessary for certain processes that happen in a brain but there are still much researchers still do not know about how this process occurs. The experiments described here will use both TMS and fMRI to explore these dynamics in greater depth. The use of TMS is not approved by the FDA for use in healthy subjects and is experimental.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

- Adult healthy volunteers, men and women, as well as people from various racial and ethnic backgrounds.
- Be between the ages of 18 and 50 years, with no past or current mental illness.
- Ability to tolerate small, enclosed space without anxiety.
- Ability to understand this consent document and willingness to give signed consent.

3.2 Who cannot take part in this study?

- History of substance/alcohol dependence within the last 5 years.
- Taking psychotropic medications or any other medications that may affect the brain.
- Women of childbearing age who are pregnant or trying to become pregnant.
- History of serious neurological illness, closed-head injury, or current medical condition that could compromise brain function (e.g., liver failure).
- History of epilepsy in you or your immediate family.
- No metals or implants in your body that might affect the magnetic energy from the scan (e.g., pacemakers, artificial joints, aneurysm clips, etc.) or any other metal risks as determined by the MRI safety screen.

3.3 How many people are expected to take part in this study?

A total of 60 healthy adults are expected to participate.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

All study procedures will follow the University of Michigan's COVID-19 safety guidelines. The study will be done in 5-6 visits, spread out over a few weeks.

Visit 1, Part 1 & Part 2 – Screening & Assessment (remote video conference and Rachel Upjohn Building), approximately 2-2 ½ hours

Visit 2 – Baseline fMRI scan, followed by TMS session (fMRI Laboratory, UM North Campus, Bonisteel Interdisciplinary Research Building), approximately 2-3 hours
Visit 3, 4 & 5 – Experimental TMS session, followed by fMRI scan (fMRI Laboratory, UM North Campus, Bonisteel Interdisciplinary Research Building), approximately 2-3 hours

Visit 1, Part 1:
Part 1 of the first session (or two) can be conducted via remote video conference or as an in-person visit at the Rachel Upjohn Building (RUB) located on the East Medical Campus. This visit may take up to 1 ½ hours to complete. Video conference sessions will use a secure link that will protect your confidentiality to the degree permitted by the technology being used. Although every reasonable effort has been taken, confidentiality during actual web-based or phone communication procedures cannot be guaranteed.

This session will several screening assessments, which involve asking you questions about your mood, feelings, drug and alcohol use, and any psychiatric symptoms you may have experienced in your life. We will ask you to complete some forms online with additional questions about your medical history. Finally, we will complete fMRI and TMS safety screens and provide you with your TMS/fMRI schedule.

If you are found to be a good match for the study, you will be scheduled to come into the RUB to complete Part 2. Not all participants will be eligible to move forward in this study.

Visit 1, Part 2:
The second part of the assessments will be scheduled at the Rachel Upjohn Building and may take up to 1 hour to complete. This visit will include the following:

Memory task practice & Mock scanner (preparation for MRI scans)
Study staff will teach you how to do a short-term 'working memory" task, then you will be given about 5-10 minutes to practice. After you've become comfortable with the task, you will then enter a "mock scanner" to do the task there. The mock scanner has a moving table that takes you inside a large tube, similar to the real MRI scanner. Study staff will stay in the room with you during this process. In addition to learning the task, the mock scanner will help to familiarize yourself with the scanner environment and de-sensitize you to the actual scanner.

Visit 2: Baseline MRI and TMS session (up to 2 weeks after visit 1):
Safety assessments
You will be scheduled to go to the fMRI Lab on the UM North Campus. Study staff will meet you there and, if needed, give you a parking pass then escort you inside. They will ask you about your sleep patterns and caffeine, alcohol, nicotine use. Mandatory MRI and TMS safety screens will be completed again to make sure nothing has changed since the initial assessment, then you will be prepped for the MRI scan, ensuring that all metal and magnetic-sensitive objects (e.g., jewelry, glasses, keys) are removed from your person. The MRI tech will review the MRI safety screening form you completed during your interview and may ask you some additional questions to make sure it is safe for you to undergo an MRI scan. Lockers are provided at the fMRI lab to store personal items such as wallets, cell phones, etc. If you are a woman of childbearing age and are unsure of your current pregnancy status, you will be offered a urine pregnancy test.

Baseline fMRI
You will then go into a magnetic resonance scanner. You will lie on the bed of the scanner, arranged so that you feel as comfortable as possible. You may be asked to breathe into a tube attached to a meter which will measure the amount of carbon dioxide (CO2) in your blood. You will be given a response claw with buttons to wear on your hands to enable you to make button-press responses to the tasks you learned at Visit 1. Once settled, the bed will move inside the scanner (which looks like a long tube, approximately 3 feet in diameter). You will be able to communicate via intercom with the MRI technician running the scanner in the control room. You are also given a squeeze bulb to hold in case you should need to gain the attention of the technicians quickly, triggering an alarm in the control room by squeezing the bulb. Inside the scanner, you will hear periodic loud noises, and we will talk to you over the intercom at times. The task will be presented to you on a computer screen inside the scanner, and you will make responses, with the claw.

Baseline TMS
Following the completion of this fMRI, you will go to the TMS session.

You will be seated in a chair. Since TMS produces a loud clicking sound, you will need to wear protective ear plugs. TMS does not require anesthesia or sedation, so you will be awake during the process. Once you are seated comfortably, study staff will place 2 stick-on electrode pads onto your right hand, and another on your right elbow. These electrodes will measure muscle activity in these areas. Then, the magnetic coil will be placed over the side of your head. Stimulation is delivered via magnetic "pulses" from a TMS coil. The study staffer will use *single* pulses to determine the *intensity* of stimulation needed for you; this is because everyone's brain is different. To determine your individual intensity prior to the experiment, researchers will be stimulating a part of your brain called the motor cortex. During this stimulation, these single pulses will cause movements in your fingers and the muscles of your arm and hand. This is normal and is how we determine the level at which the TMS machine should be set specifically for you prior to the experiment. After your *intensity* is determined for you, we will set the TMS machine at your specific intensity when we stimulate the two different target areas on subsequent, experimental days. (Visits 3, 4 & 5).

At this second visit, we will also demonstrate for you the how TMS will feel in those subsequent visits, when we will stimulate with rapid, repeated pulses. This is a form of TMS called 'theta burst stimulation,' and it may be somewhat uncomfortable. It does not last long (a little over 3 minutes), but if you find it too uncomfortable, you will be free to withdraw from the study at this point (and you will be reimbursed for your 2 visits).

Visits 3, 4 & 5: Experimental TMS & fMRI Sessions:
All experimental TMS & fMRI sessions involved in visits 3, 4 & 5 are the same except that each day we will be targeting different brain regions. These visits will occur within about 1 week, depending on when we can schedule the MRI.

Safety assessments
All safety assessments from Visit 2 will be repeated for each of these visits.

Experimental TMS sessions
In addition to the procedures we followed on Visit 2, we will complete some extra steps to prepare you for the TMS on Visits 3, 4 & 5. You will be asked to wear a small headband, so the computer can track the location of your head and allow us to position the TMS coil. We will stimulate a position on your scalp with the TMS coil,

using a type of stimulation called theta burst stimulation. You will experience a rapid sequence of sharp taps, that will go on and off for about 3 minutes. These taps may be slightly uncomfortable, even slightly painful. You will be able to stop the procedure at any time. While you are receiving the TMS, you may be doing a computer-based task, such as a short memory task.

Experimental fMRI session
The fMRI sessions on each visit will follow immediately after the TMS session. fMRI sessions will be identical to Visit 2's session.

4.2 How much of my time will be needed to take part in this study?
You will complete the following (5) 2-3 hour study visits, at two separate UM facilities. Total time needed is approximately 10-15 hours.

4.3 When will my participation in the study be over?
Your participation will be over after completion of Visit 5.

4.4 What will happen with my information used in this study?
With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies. Your identifiable private information will be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent. See the end of this document for more information.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Risks associated with screening and survey data collection
Loss of confidentiality around sensitive information (rare, not serious).

To minimize risk*:* All subjects are assigned research numbers, and all research information collected is linked to you only by this number. Great care is taken to remove all identifying information from research records. A single tracking file contains links to the research records and subject codes. Recruitment tracking files are kept only for the duration of the study. Paper records are kept in locked file drawers in a locked room, to which only authorized research personnel have access. Paper records with identifying information (consent form, payment records) are kept in locked file cabinets, physically separate from the research records. Computer records with identifying information are kept on secure, password protected servers. Staff are trained to scrupulously protect the confidentiality of sensitive information and take care to limit the printing of documents with identifying information and to avoid unnecessary discussion of subject names.

Risks associated with TMS
(1) TMS may increase the risk of a seizure. However, when international safety guidelines for TMS are followed, the risk is very small.

To minimize risk: We will follow the most current safety recommendations for TMS and we will also exclude anyone with an increased risk of developing a seizure. In addition, the staff are trained to

monitor for signs of a seizure during the TMS and to provide first aid in the event of a seizure during a session.

There are certain conditions that may increase your risk of having a seizure, and we will ask you about these conditions before each TMS session. Depending upon your response, we may not allow you to do the TMS/MRI session that day, and we may need to reschedule it, *if: (1) you have consumed any alcohol within the last 24 hours, (2) you feel that you have been deprived of sleep within the last 24-48 hours, or (3) you have taken any drugs known to cause changes in the brain.*

(2) Pain and discomfort around the stimulation site and on your scalp is a common side effect caused by muscle contractions
during the TMS treatment. The pain usually disappears when stimulation ceases.

To minimize risk: The procedure can be discontinued if the stimulation is too painful.

(3) Headache and neck pain caused by muscular contractions (twitches) are also common side effects reported after TMS. These side effects usually last up to a few hours on the day of stimulation.

To manage risk: Headache and neck pain are managed easily with non-prescription pain relievers such as aspirin, acetaminophen (Tylenol), or ibuprofen. In the unlikely event that the headache persists on the following day, you will be told to contact the investigators.

(4) When producing a magnetic pulse, the stimulating coil creates a series of brief loud clicks.

To minimize risk*:* Although there is no evidence of hearing loss in people exposed to TMS, earplugs will be used during TMS as a precautionary measure.

(5) *Fainting*. Sometimes, participants become light-headed, and will faint during the procedure.

To minimize this risk: Subjects are encouraged to be well-hydrated in advance of the sessions. During breaks and upon completion of the protocol, they are advised to rise slowly from the chair and observed carefully for any signs of fading consciousness.

(6) For women of child-bearing potential: It is unknown if TMS can pose a risk to fetuses.

To minimize risk: You should not take part in this study if you are pregnant or trying to become pregnant.

Risks Associated with MRI Scanning

(1) Discomfort or anxiety (occasional, not serious).
There is a minor risk of discomfort or anxiety/panic from being in the confined space of the MRI scanner.

To minimize risk: Discomfort and anxiety from the scanner will be minimized by custom pads and pillows to make you as comfortable as possible. You can communicate with the study staff and the MRI technician via an intercom. You are also given a squeeze ball to hold which can trigger an audible alarm at any time. Before you are entered into the tunnel of the scanner, you will be reminded that you are free to stop the study at any time if you become too uncomfortable.

(2) Peripheral nerve stimulation (rare, not serious).
Fast imaging sequences, like the ones we use in this study, have the potential to induce peripheral nerve stimulation (PNS). PNS can be described as a light touching sensation on the skin surface, much like the “pins

and needles" feeling you get right before your arm falls asleep. This may cause some mild discomfort but is not harmful to you.

To minimize risk: The MRI machine is operated within FDA guidelines so the potential for inducing PNS is low.

(3) Slight dizziness, light-headedness or nausea (rare, not serious).
Sometimes people report these symptoms during or immediately after the scanning session.

To minimize risk: If you feel light-headed, we will be there to guide you to get up from the scanner bed very slowly, resting in a seated position with your feet dangling for several seconds or more before attempting to stand.

(4) Incidental finding (rare, serious).
Sometimes the MRI image may reveal a minor or significant lesion in the brain, e. g. a tumor, previously unknown to you, requiring additional follow-up.

To minimize risk: You will be made aware of the risk of learning about an abnormal finding in the study that might require further evaluation with a clinical MRI. We will also inform you that many abnormalities will not be picked up in this study, since the scanning sequences we use are not sensitive to many forms of brain pathology. However, in the event that we do find something that is very obvious, such as a large tumor, we will personally contact you by phone call, or in person, and let you know about it. No diagnosis will be offered, but we may recommend that you follow-up with your primary care clinician.

(5) Hearing damage (very rare, serious).
Due to the loud, vibrating noises made by the scanner.

To minimize risk: You will wear earplugs and/or earphones throughout the procedure, which reduce the high decibel sounds, but still enable you to hear the intercom and respond to the questions from the research staff while you are in the scanner.

(6) Injury (very rare, serious).
Because the strong electromagnetic fields can move metal objects and cause heating, there is a risk that loose objects (jewelry, keys) outside the body could be accelerated by the magnetic field, striking and injury you. There is also a risk that the magnetic fields could disturb a metal fragment in the body, interfere with an implanted device, such as a pacemaker or neurostimulator, or cause metal (including foil-backed medication patches) on or in the body to heat up, causing harm.

To minimize risk: The MRI suite is kept clear of all objects that could be picked up by the magnetic field, and you will complete a comprehensive MRI safety screening form prior to entering the scanner, which is reviewed by the MRI technologist (trained in clinical MRI) before any scanning begins.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. In the future, others may benefit based on information we learn about brain and TMS functions.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
There are no alternatives to this study. Your do not have to participate in this study. Your participation in it is completely voluntary. If you are a patient at UM and/or the Department of Psychiatry and you decide not to participate in this study, your decision will not affect your care.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No, there is no harm to you if you decide to leave the study, or the scan, early.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs or billings for this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
Yes, you will be paid for your time as follows:

$ 20 for completion of Visit 1/Assessment Session
$ 50 for each TMS/MRI session (visits 2-5)
$220 Total

You will be paid (either by gift card or check) when you complete the study, at the end of Visit 5. If you leave the study before completing all the sessions, you will be paid for those sessions you have completed.

8.3 Who could profit or financially benefit from the study results?
We do not expect that any person, institution, or company will profit or financially benefit from this study. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
You are assigned a research number and all research information collected is linked to you only by this number. Great care is taken to remove all identifying information from research records. A single tracking file contains links to the research records and subject codes. Paper records are kept in locked file drawers to which only authorized research personnel have access. Paper records with identifying information (consent form, payment records, etc.) are kept in locked file cabinets, physically separate from the research records. Computer records with identifying information are kept on secure, password protected servers. Staff are trained to scrupulously protect the confidentiality of sensitive information, and take care to limit the printing of documents with identifying information and to avoid unnecessary discussion of subject names. None of your research information will made a part of your regular medical record.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Future IRB-approved research studies
- Information about your study participation may be included in your regular Michigan Medicine medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.
- De-identified data may be shared with other investigators seeking to understand higher brain function and neuropsychiatric disorders.
- The results of this study could be published in an article but would not include any information that would let others know who you are.

9.3 National Institute of Mental Health Data Archive (NDA)

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share de-identified (no PHI) information with each other. Researchers will send de-identified information to the NDA. Other researchers nationwide can then access study data for research

purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. You will not be contacted directly about the data you contributed to NDA. You may decide now or later that you do not want to share your information using the NDA. If so, contact the researchers who conducted this study. However, the NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at **http://data-archive.nimh.gov**.

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, see below); 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.). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

9.4 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission, or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the Michigan Medicine, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.5 When does my permission to use my PHI expire?
Your permission expires at the end of the study unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	Stephan F. Taylor, MD
Mailing Address:	4250 Plymouth Rd, Ann Arbor, MI 48109
Telephone/email:	(734) 936-4955/sftaylor@med.umich.edu
Study Coordinator:	Laura M. Stchur, LMSW
Mailing Address:	4250 Plymouth Rd, Ann Arbor, MI 48109
Telephone/email:	(734) 936-1323/lmarine@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

You will receive a copy of the signed and dated informed consent.

Your signature in the next section means that you have received copies of all the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular Michigan Medicine medical record [MiChart].*

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Use of your data for unspecified future research

When the study is completed, which means that we have collected all the data we need, conducted our analyses, and regulatory agencies do not need to examine our records connected to your identifying information, we will remove personal identifiers from your data, so that people cannot easily connect your data with you. This will occur about 2-3 years after the study is completed. We would like to continue to use your data for future research, with University of Michigan investigators, for additional analyses. Your data includes information we have collected about you in the study, our measurements of your behavior and your fMRI scan data. The future research may be similar to this study or may be completely different.

If you do not want us to continue to use your data this way, then you should not participate in this research study. Even if you give us permission now to keep this information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your data, we may not be able to take the information out of our research.

We are also asking for your explicit permission to share your data with other researchers who are not connected with this study, so that they can use it in their research. By 'sharing,' we mean transferring the data to other researchers or to a central database. Their research may be similar to this study or may be completely different. Once we have shared your medical information with other researchers, we will not be able to get it back. This sharing includes putting your data in a public database run by the National Institute of Mental Health, the sponsor of this research study. This database is known as the National Institute of Mental Health Data Archive, or NDA, and the NIMH requires that we upload your data to this archive, with your permission.

The risk posed to you by us sharing your data will be very small. We will minimize that risk by carefully removing information that could be used to link back to you, such as your birthdate, your address, or your medical record number. We may have a special 'key' that links the data we upload to a central database, which we maintain while we are collecting the data, so that we don't mix up different subjects during the upload process. Investigators using these central databases will not have access to the key linking you to your data, and when the study is completed, we will destroy this link. An additional precaution is that no data will be shared from the central database without an agreement by stewards of the central databank to prevent investigators from even attempting to identify subjects. You should also know that strict rules govern how we, and others, use data we acquire in research studies, and people who use your data must abide by these rules.

You will not find out the results of future research on your data. Allowing us to do future research on this information will not benefit you directly.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

Sig-D

Consent to Collect Data for Sharing and Unspecified Future Research

This project involves the option to allow the study team to share my data with other researchers outside the University of Michigan, such as the NIMH Data Archive, for use in future research. I understand that it is my choice whether or not to allow future use of my data. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team share my data for future research.

_____ No, I do not agree to let the study team share my data for future research.

Print Legal Name: _____

Signature: _____