Official Title: Multi-modal Assessment of GABA Function in Psychosis

NCT#NCT04004416

Date: 3/10/2025

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY – ADULT VERSION

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Multi-modal assessment of GABA function in psychosis

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. This form contains important information that will help you decide whether to join the study. All of the information is important for you to review but here are some key points to keep in mind:

- Taking part in this study is completely voluntary.
  - If you decide to participate, you are free to leave at any time.
  - If you decide not to participate, your decision will not affect your clinical care.
- The purpose of this study is to better understand mental illness. The types of mental illness we are studying includes conditions with 'psychosis', which means a break from reality. This would include disorders such as schizophrenia, schizoaffective disorder, and mood disorders.
- People between the ages of 16 and 60, who have a psychotic illness or risk signs of a psychotic illness, can participate. We are also looking for people without any psychiatric illness or risk signs, allowing us to compare their brains.
- The study will involves the following procedures:
  - Remote video and in-person assessment study visit(s): diagnostic interview and several questionnaires to see if you're a good match.
  - Magnetic resonance imaging (MRI) Sessions: You will then have 2 MRI scan sessions. Before each scan, you will complete some questionnaires, and be given a dose of medication. In one session, this dose will consist of lorazepam (also known as Ativan), and in the other session, it will be an inactive medication (placebo). Neither you nor the research staff will be told which you are receiving until after both sessions are completed. The MRI will allow us to see how your brain chemicals respond to the medication. Before you go into the MRI scanner, a trained medical assistant may take a small sample of your blood for study analysis.
  - After you complete all the sessions, you will be compensated for your time.

There are no direct benefits for you in this study. There are some minimal risks associated with the assessments, MRI, or lorazepam which are outlined in full in Sect 5.1. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this study is to better understand mental illness. The types of mental illness we are studying involve a 'psychosis,' which means some kind of break from reality. Psychosis includes conditions like schizophrenia, schizoaffective disorder, and mood disorders. We will use magnetic resonance imaging (MRI) to study your brain, so we can "see the brain at work." Before the MRI scan, we will also give you a dose of lorazepam. This medication is sometimes used to treat your disorder (if you are a patient who has one of those disorders), but we will not be giving it as a treatment in this study; rather, you will get a single dose of the medication, which will allow us to see how your brain chemicals respond to the lorazepam. You will have two MRI sessions, but you will be given the medication in only one session. In the other session, you will receive a placebo.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you do not 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?

People between the ages of 16 and 60 who have a psychotic illness or who are at-risk for developing a psychotic illness can participate. If you are a patient and are currently taking prescribed medications, you may participate as long as you have been stable for at least 1 month and your prescriber has not needed to make any medication changes to counteract worsening symptoms. However, something like reducing your dose because you are doing well would not disqualify you from participating. We are also looking for people without any psychiatric illness or at-risk signs, allowing us to compare their brains.

3.2 Who cannot take part in this study?

If you actively abuse substances, including alcohol, or if you have a chronic medical condition, a developmental disability, an organic brain syndrome, such as depression due to a closed head injury, you may not be eligible to participate. Because the MRI scanner is a small, enclosed space, you must be able to tolerate enclosed spaces without anxiety. You should not have any metals or implants within your body that might be affected by the magnetic energy from the scan, which could cause you serious harm. If you are a woman of child-bearing potential, you cannot be pregnant or trying to become pregnant.

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

We expect to enroll a total of 232 participants.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

The study will be done in 4-5 sessions, spread out over a few weeks. *All study procedures will follow the University of Michigan's COVID-19 safety guidelines.*

Consent Process: This session can be conducted either via remote video conference or as an in-person visit at the Rachel Upjohn Building (RUB) located on the East Medical Campus. 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.
During this session we will review the consent, obtain an electronic signature, and obtain demographic and medical history information. We will ask you some safety question for the fMRI scans and questionnaires* will be completed online through a secure web-link which we will email you.

If you have been a participant in the Longitudinal Study of Bipolar Disorder (McInnis, HUM0000606), Neural Mechanisms of Gaze Perception in Psychosis (Tso, HUM00080457), or the Psych Registry (Taylor, HUM00123648), we may be able to use some of the information gathered in those studies for the current study.

***Screening assessment, Part 1:** Part 1 is a clinical interview that will be conducted either via remote video conference or as an in-person visit at the Rachel Upjohn Building (RUB) located on the East Medical Campus. If more than one assessment day is needed, subsequent days will also be scheduled this way.

We will ask you questions about your moods, feelings, and any psychiatric symptoms you may or may not have. 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. The clinical interview will help to determine if you are a good fit for the study and this will be further evaluated when you come into the building in person for the additional steps.

**Questionnaires/assessments may need to be repeated if too much time has passed before MRI #1.*

Video Recording:
We would like to request your permission to video record a portion of the Assessment Session. We will use these recordings to make sure the assessments are of the highest quality across different clinicians. They will remain on a secured drive for the duration of the study. After that, they will be destroyed, although we may contact you about keeping the video recording for training purposes outside the study. If you do not wish for us to record the clinical interviews, you can still participate in the study.

Please indicate below if we have your permission for each by selecting either “yes” or “no” and initialing below:

Participant	
Yes	**No**
Initials: _____	

Screening assessment, Part 2: Part 2 is an in-person visit only and will be scheduled at the Rachel Upjohn Building. This visit will include the following:

- We will give you a few memory and thinking tests, similar to what you might have taken when you were in school. You will also be given some picture tasks to look at on a computer. The pictures you will see include images of people and places, some may be very unpleasant, such as people with very bad, bloody injuries, and some will be very pleasant and happy. We will ask you to push a button about whether you find the picture pleasant, unpleasant or neither.
- To prepare you for the MRI scanner, we will have you go into a 'mock scanner' which is similar to the real scanner. It will allow you to get used to this environment and to practice the task you will do in the real scanner. Study staff will affirm with you that you are eligible for the scan and feel comfortable in the scanner.
- If you think you might be pregnant, you will be given the option to get a urine pregnancy test.

MRI #1 & #2:
The two MRI sessions will occur at the MRI laboratory, which is located on the North Campus, and will be scheduled about 4 weeks apart. If you are a participant who menstrates, we will ask you the date of your last menstrual period because this cycle affects the measurement of the MRS (magnetic resonance spectroscopy) GABA levels we are obtaining. You should come to these sessions wearing comfortable clothing and no metal jewelry of any kind (including any piercings).

Procedures for each MRI session will be identical:

- Because the lorazepam we give you can make you drowsy, you will be required to have another adult drive you to and from both sessions. If you do not have transportation, we can provide transportation for you.
- You will be asked to complete and sign the fMRI Lab's safety screening form.
- You will be asked to provide a urine sample for a drug screen. All participants of child bearing potential will also be given a urine pregnancy test.
- You will be asked to complete a number of questionnaires about your mood and, if you're taking medication(s), any side effects you may be having from them.
- You will then receive a dose of medication called lorazepam, or a dose of inactive medication (placebo), but neither you nor the research staff will be told which you are receiving. You will receive one of these in the first MRI session and the other in the second MRI session. It is important that you not know which of these sessions may contain the active medication, as such knowledge may affect how you respond in the study. However, in the event of any adverse event, the research staff can be made immediately aware of which medication you received. At the end of the study, we will tell you which session involved the active dose.
- After taking your dose, you will need to sit quietly for approximately 90 minutes before entering the MRI scanner.
- You will have your vital signs (blood pressure, heart rate, etc.) taken, then a trained medical assistant may draw a small amount of blood (8 ml or about ½ tablespoon), which will be used to measure drug levels and markers of inflammation in your blood.

- After 90 minutes, you will then go into a magnetic resonance scanner room. 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. For some scans, a strap will go around your chest and a small plastic tube will clip to one of your fingers. You will be given earplugs and soft foam padding will be placed around your head to protect your ears from the loud, vibrating noises throughout the procedure. The bed will move inside the scanner (which looks like a long tube, approximately 3 feet in diameter), and an intercom system will allow you to communicate with us in a nearby room.
- The same pleasant/unpleasant pictures you saw and rated on the Assessment Day will be projected to you while you are inside the scanner. When required, you will make your responses by pressing a button inside a "button glove" that's attached to your hand.
- At the conclusion of the MRI scan, we will ask you questions about your MRI experience.

Blood Draw:
We would like to request your permission to obtain a blood sample at MRI #1 and MRI #2. A trained medical assistant would draw a small amount of blood (8 ml or about ½ tablespoon) at each MRI visit. If you do not wish to provide a blood sample, you can still participate in the study.

Please indicate below if we have your permission for collecting a blood sample by selecting either "yes" or "no" and initialing below:

Participant	
Yes	**No**
Initials: _____	

As a subject participating in this research study, you have certain responsibilities which are important to this study, such as ensuring that you arrive at all your scheduled appointments and your MRI scans on time. If you need to reschedule an appointment or choose to cancel your participation altogether, we ask that you contact the study staff to let us know.

4.2 How much of my time will be needed to take part in this study?

We estimate the following:

- Consent Process: 1-1.5 hours
- Screening, Part 1: 2-4 hours (may be scheduled across multiple days)
- Screening, Part 2: 2-3 hours
- MRI#1: 4 hours (2 hrs prep time + 2 hrs in scanner)
- MRI#2: 4 hours (2 hrs prep time + 2 hrs in scanner)

Total time = up to 16.5 hours scheduled over span of about 4-6 weeks

4.3 When will my participation in the study be over?
After you complete MRI#2 and all remaining assessments.

4.4 What will happen with my information and/or biospecimens used in this study?
The data we collect, from the MRI scanning and questionnaires, will be uploaded to the National Institutes of Mental Health Data Archive. However, we will remove information that could be used to identify you, such as your name and birthdate, from the records we upload to the data archive. We may also share your data, with identifiers removed, with other researchers for future studies, which might not be directly related to the study proposed here.

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?
The known or expected risks are listed below, along with the steps taken to minimize these risks:

Risk of boredom, fatigue, or discomfort (likely, not serious)
It is possible that you will become fatigued, frustrated, or uncomfortable answering sensitive questions about your mental health history.

To minimize risk: You may request a break from the procedures and/or may decline to answer any questions that make you feel uncomfortable.

Loss of confidentiality around sensitive information (rare, not serious)

To minimize risk: You 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. Any information we obtained from you at the phone screen are kept only for the duration of recruitment. 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. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

Risk to pregnancy
You will not be enrolled in this study if you are pregnant or trying to become pregnant.

To minimize risk: All participants of child bearing potential will be required to have a negative urine pregnancy on the day of each MRI session.

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 your MRI image 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, the Principal Investigator 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 injuring 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.

Risk from lorazepam

(1) Common side effects (5 - 15 %): Drowsiness, coordination problems, impaired concentration; risks could be compounded by interactions with other sedating drugs and/or alcohol.
(2) Uncommon side effects (<1%): Agitation and lack of impulse control.
(3) Uncommon side effects (< 0.1 %): Breathing problems, confusion, memory problems, allergic reactions.
(4) Lorazepam can interact with other drugs, including alcohol, to worsen sedation or impair your ability to drive or operate heavy machinery. It is very important that you let us know about any and all medications you are taking, your alcohol consumption, and any substances you consume on a periodic basis, because they may interact with lorazepam. Even if you take these substances within the 48 hours before or following your MRI session, you may be at risk for developing some side effects.

To minimize risk: At the low dose selected for this study, we expect very few side effects beyond mild sedation. A review of basic health status will ensure that you have no conditions, such as liver failure, that impair the metabolism of lorazepam. We will carefully monitor you to make sure that you are not experiencing excessive sedation while you are in the scanner. At the completion of the study, study staff will assess your sedation and look for any mental status changes.

To further minimize risk: As noted above, you will be required to have another adult accompany you home after each scanning session, regardless of any reported side effects. If you do not have access to transportation, we can provide you with a cab directly to and from your home. If you were to have a more serious reaction, such as an acute confusional state or disinhibited behavior, we would arrange for urgent transportation for you to be evaluated in the UMHS Emergency room. Lastly, you will be warned not to consume any alcohol for 48 hours before or after the session to avoid untoward effects from any use of alcohol after the study is done.

Risk due to blood draw

There is a small risk of bleeding, bruising, infection or fainting from the injection.

To minimize risk: An experienced technologist will administer the blood draw and sterile procedures will be used to minimize the chance of infection.

Risk associated with viewing potentially disturbing material (pictures from the computer task)

There is a risk that you may become uncomfortable viewing the negative content of these images.

To minimize risk: The research team has had extensive experience with this image set, in over 200 subjects, including persons with psychiatric diagnoses such as schizophrenia and post-traumatic stress disorder. This image set has been used at laboratories all over the world, and subjects tolerate the images without significant difficulty. The most aversive pictures consist of images that one would encounter in a "gory R-rated movie". It's important to know that you maintain control over the experience (and we encourage you to close your eyes for any image you find too intense) and you can terminate the study at any time. The images and the protocol have been presented to the members of the University of Michigan IRB (Internal Review Board),

as well as community members at the local mental health agency. If you become upset while viewing the pictures, the research staff would be available to counsel you and provide positive coping strategies to deal with the experience.

Risk of delay of treatment

During the time you are participating in the study, you might experience a delay in treatment you would otherwise receive.

To minimize risk: You will be carefully assessed before you enter the study, and if we do not think that it is safe for you to delay treatment, we will help you get that treatment and not enroll you in the study until you are stable enough to participate. The time period of the study (about 4-6 weeks) is very short relative to the course of psychosis and the initiation of treatment in standard clinical settings. Because of diagnostic uncertainty in early psychosis patients, it is often appropriate to observe a patient over a several month period to determine the need for antipsychotic medication. However, if you become too unstable or impaired to participate, you will be withdrawn from the study.

Risk of symptom worsening during study procedures

There is a small chance that your symptoms may worsen during the study procedures.

To minimize risk (for worsening symptoms): As mentioned above, if your condition is not stable enough to participate, we will not enroll you in the study. Trained study staff will monitor you closely during the study procedures, and at several points, we will have you complete very short questions about your mood and symptom levels. If your symptoms were to become particularly severe, such as strong feelings of suicide, we may have you go to the emergency room for additional evaluation to ensure your safety. If you are having active suicidal thoughts, we will not enroll you in the study, so it is unlikely that these thoughts will crop up during the study.

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 doctor**.**

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 prior 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?

There are no direct benefits for you in this research. However, this study may benefit society, in general, and in brain science specifically, because it is designed to contribute new knowledge to the understanding of psychosis.

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. You do not have to participate in this study. Your participation in it is completely voluntary. If you are a patient at the PREP (Program for Risk Evaluation and Prevention) clinic and you decide not to participate in this study, you may still continue your treatment there.

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, your reasons 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.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- 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:

- Consent & Screening: $15/hr
- MRI #1 $60 + $15 for blood draw
- MRI #2 $60 + $15 for blood draw

Estimated Total: $225-$265

You will be paid (either by gift card or check) when you complete the study. If you leave the study before completing all the sessions, you will be paid for those sessions you have completed. If you are coming outside the radius which Green Cab travels, we will provide mileage reimbursement as well.

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. A signed copy of this consent will be entered into your medical record, but information specific to the research (e.g., urine drug screen or pregnancy test results) will not.

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

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

- All records relating to your condition, the treatment you have received, and your response to the treatment
- 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 these conditions or their treatment.
- The researchers may need to use the information for 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 website 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 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 HUM 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 of 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

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 Full Legal Name (*including middle name*):

_____

Signature: _____

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

Consent/Assent to Collect and Share for Unspecified Future Research

This project involves the option to allow the study team to keep your de-identified data for use in future research and to share them with other researchers, such as through the NIMH Data Archive. I understand that it is my choice whether or not to allow future use of my specimens. 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.

Please indicate below if we have your permission to keep your data for future use and to share it with other researchers by selecting either “yes” or “no” and signing below:

Participant	
Yes	**No**

_____ _____

Signature Date of Signature (mm/dd/yyyy)

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/yyyy): _____