This is a patient consent for a medical procedure called Transcranial Magnetic Stimulation (TMS). This consent outlines the treatment that the psychiatric provider has prescribed, the risks of this treatment, the potential benefits of this treatment, and any alternative treatments that are available if I decide not to be treated with TMS. The term “psychiatric provider” includes both psychiatrists, and nurse practitioners. For the purposes of this form, the word “I” refers to either the patient receiving treatment and/or the adult caregiver who is a legal guardian of the patient.

**TMS is FDA cleared to treat refractory Major Depressive Disorder (depression that has not responded adequately to medications and therapy) in adults only, any other use would be considered off label.** Offl label meaning that the FDA has not approved TMS for any other use. The FDA advises that two different antidepressants be used at a high enough dose for a long enough period of time and not be successful prior to trying TMS. Therapy may be beneficial as well in treating depression. There are alternatives to TMS, including no TMS, therapy, alternative medications, and ECT. I also know that I can obtain a second opinion regarding diagnosis and treatment options.

I understand that:

1. A TMS treatment session is performed with an FDA cleared system that delivers pulsed magnetic stimulations over the scalp and into the brain. The magnetic fields are of a similar in strength as those used in magnetic resonance imaging (MRI) machines.

2. TMS has been shown to be a relatively safe and effective treatment for patients with depression.

3. TMS was shown to reduce depressive symptoms in adults who had been treated with antidepressants and medicine but did not get adequately better.

4. I understand that the TMS treatment that I undergo may include off-label use of TMS. Off-label device use (OLDU) means using an FDA cleared device for a different condition, or using a device settings, that have not been specifically cleared by the FDA. OLDU is common, it occurs in every specialty of medicine. After a device has been cleared for one condition, clinicians are not limited to the FDA-approved indications and are allowed to use it for any condition if, in their professional judgment, it is reasonably safe and effective, and potential risks outweigh potential benefits in the clinician’s determination. Commonly used off-label uses for TMS include use for many other psychiatric diagnoses (obsessive compulsive disorder, ADHD, Anxiety Disorders, Autism, etc.), varying frequencies and amplitude of stimulation, varying positions on the head to stimulate different parts of the brain, shorter or extended protocols, more or less time between stimulation sessions, and/or bilateral treatments.

5. During a TMS treatment session, the psychiatric provider or a qualified member of the clinic staff will place the magnetic coil against the scalp over the treatment area. The magnetic field produced by the device is targeted over areas of the brain that the psychiatric provider believes may be affected in the patient's condition.

6. We will then position the patient’s head and TMS device and introduce a series of single magnetic pulses over the motor cortex of the brain to find the right stimulation dose. There will be a clicking sound and the patient may feel a tapping like sensation on the scalp. The psychiatric provider will adjust the device to give enough energy into the are of the brain that controls the right hand so that the right hand makes a twitching movement. The amount of energy needed for this stimulation is called the “motor threshold.” (MT). MT’s differ between patients, and the treatments are individualized.7**. TMS risks:** Long term side effects are unknown at this time.The changes made to the brain are expected to be permanent and beneficial, but may be permanent and harmful. There is a risk that measurements taken are not accurate and that the wrong area of the brain is treated. There is risk that the magnetic energy coil is not placed correctly and is not delivered to the expected treatment area in the brain. I understand that I should inform my psychiatric provider or a member of the TMS Therapeutic staff of any side effects. There may be discomfort and headaches over time.TMS is not effective for all patients.. Any signs or symptoms of a worsening condition should be reported immediately to your psychiatric provider. It may be beneficial to ask a family member or caregiver to monitor your symptoms to help you spot any signs of worsening problems. Please understand that many but not all patients benefit from TMS treatment and that it may take up to the fourth week of treatment for it to work or it may never work at all. Some patients may experience results in less time while others may take longer.

8. Then the magnetic coil will be moved, and the patient will receive the treatment as a series of “pulses” for 4 seconds every 26 seconds, but other patterns may be used off label. Treatment is to the left front side of the patient’s head and will take between 6 and 40 minutes.the patient will receive these treatments 5 times a week for approximately 4-6 weeks (20-30 treatments). My psychiatric provider will evaluate the patient as necessary during this treatment course and may be scheduled when requested. The psychiatric provider may make off label changes to the treatment settings, add additional treatments, stimulate a different place on the head in order to get a more effective outcome.

9. During the treatment,the patient may experience headaches, tooth pain, muscle contractions, tapping or uncomfortable sensations at the treatment site when the stimulator is on. These were felt by about 1/3 of patients in the research studies. The patient (if able) should inform the psychiatric provider or staff if the sensation is uncomfortable or painful. My psychiatric provider or staff may then adjust the dose or change the location of the coil to make the procedure more comfortable.

10. TMS should not be administered to anyone who has magnetic metal in their head or within 12 inches of the TMS coil that cannot

be removed. Failure to follow this restriction could result in serious injury or death.

111. Objects that may have this kind of metal include the below, please initial each to attest that I do not, and/or the patient does not have any of the following:

\_\_\_\_\_ No aneurysm clips or coils \_\_\_\_\_ No pellets, bullets, or metallic fragments

\_\_\_\_\_ No implanted stimulator or pacemaker \_\_\_\_\_ No other metal devices or objects implanted in the head

\_\_\_\_\_ No electrodes to monitor brain activity \_\_\_\_\_ No magnetic implants in the patient’s ears or eyes

\_\_\_\_\_ No bullet or shrapnel fragments \_\_\_\_\_ No magnetically active dental implants

12. My psychiatric provider and the staff will do their best to move the coil carefully over the patient’s head, although rare, the patient stands a chance of getting hit in the head by the magnet during positioning (this occurs very rarely).

13. There is no guarantee that this treatment will improve the condition, TMS is not effective for every patient. I will tell the psychiatric provider right away if I have any worsening depression or unusual behavior.

14. Seizures (sometimes called convulsions or fits) have been reported with TMS. There were no seizures in the clinical trials, which

involved over 10,000 patient treatment sessions. In a 300 patient clinical trial, no seizures were observed. But, seizures have occurred during other research and clinical use of TMS. The risk of having a seizure is very very low, but I will give the psychiatric provider complete medical information so that the level of risk can be assessed and discussed with me. The current estimated risk of seizure is 1 in 30,000 treatments (0.003%) or 1 in 1,000 patients (0.1%).

15. I understand that I can stop the treatment at any time.

16. I understand that I may be responsible for out of pocket costs for this procedure.

17. I have read the information contained in this consent form about TMS and its potential risks. I have discussed it with the psychiatric provider who has answered all questions. I understand there are other treatment options including medications, psychotherapy, and other kinds of brain stimulation like electroconvulsive therapy (ECT). These alternative treatment options may be discussed with me but I have chosen TMS.

18. I promise to inform the psychiatric provider or assistant if I experience anything uncomfortable, during or after the stimulation even if I think that it is not caused by the stimulation. Remember, TMS is optional and it is not an obligation.

I request and allow my psychiatric provider or staff to administer this treatment to me.

**By signing below I confirm that I am either the adult patient or the legal guardian of the patient and that I consent to treatment with TMS.   
  
Patient/Guardian Printed Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Patient/Guardian Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Witness Printed Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Witness Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**