TMS Consent Form
Matthew Barrett, M.D.

This is a patient consent for a medical procedure called Trans-cranial 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.** Off-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", but other patterns may be used off label. Treatment is to the left front side of the patient's head and will take between 3 and 30 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 mild 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.
11. 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 _____ Date_____

Patient/Guardian Signature _____ Date_____

Requesting Provider Printed Name _____ Date_____

Requesting Provider Signature _____ Date_____

Servicing Provider Printed Name _____ Date_____

Servicing Provider Signature _____ Date_____

BDI-II

Date:

Name: _____ Marital Status: _____ Age: _____ Sex: _____

Occupation: _____ Education: _____

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness
0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time.
3 I am so sad or unhappy that I can't stand it.

2. Pessimism
0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure
0 I do not feel like a failure.
1 I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure
0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings
0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings
0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike
0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness
0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes
0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying
0 I don't cry anymore than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

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11. Agitation

0 I am no more restless or wound up than usual.

1 I feel more restless or wound up than usual.

2 I am so restless or agitated that it's hard to stay still.

3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.

1 I am less interested in other people or things than before.

2 I have lost most of my interest in other people or things.

3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.

1 I find it more difficult to make decisions than usual.

2 I have much greater difficulty in making decisions than I used to.

3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.

1 I don't consider myself as worthwhile and useful as I used to.

2 I feel more worthless as compared to other people.

3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.

1 I have less energy than I used to have.

2 I don't have enough energy to do very much.

3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual.

1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.

2b I sleep a lot less than usual.

3a I sleep most of the day.

3b I wake up 1–2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.

1 I am more irritable than usual.

2 I am much more irritable than usual.

3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.

1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.

2b My appetite is much greater than usual.

3a I have no appetite at all.

3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.

1 I can't concentrate as well as usual.

2 It's hard to keep my mind on anything for very long.

3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.

1 I get more tired or fatigued more easily than usual.

2 I am too tired or fatigued to do a lot of the things I used to do.

3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.

1 I am less interested in sex than I used to be.

2 I am much less interested in sex now.

3 I have lost interest in sex completely.

_____ Subtotal Page 2

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_____ Total Score