TMS THERAPEUTICS IN SAN DIEGO, INC.

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Consent for Transcranial Magnetic Stimulation

This is a patient consent for a medical procedure called Transcranial Magnetic Stimulation (TMS). This consent form outlines the treatment that your doctor has prescribed for you, the risks of this treatment, the potential benefits of this treatment to you, and any alternative treatments that are available for you if you decide not to be treated with TMS.

Dr. _____ has told me that I have the following condition(s):

_____

The doctor has explained to me that:

a. A TMS treatment session is conducted using a device called a "treatment coil" or magnet that delivers pulsed magnetic fields. These magnetic fields are of a similar type and strength as those used in magnetic resonance imaging (MRI) machines.

b. TMS is a safe and effective treatment for patients with depression.

c. Specifically, TMS has been shown to relieve depressive symptoms in adult patients who have been treated with one antidepressant medication given at a high enough dosage and for a long enough period of time but did not get better.

d. At this time, the FDA approved indication for TMS does not include patients who did not get better after taking two or more antidepressant medications at a high enough dose and for a long enough period of time or who did not take any antidepressants during this current period of depression.

e. During a TMS treatment session, the doctor or a qualified member of the clinic staff will place the magnetic coil gently against my scalp on the front region of my head. The magnetic fields that are produced by the magnetic coil are pointed at a region of the brain that scientists think may be involved with depression.

f. To administer the treatment, the doctor or a qualified member of the clinic staff will first position my head in the head support system. At the first session, a procedure will be done to establish the appropriate stimulation dose. The magnetic coil will be placed on the side of my head, and I will hear a clicking sound and feel a sensation on my scalp. The doctor will then adjust the TMS coil so that the device will give just enough energy to send electromagnetic pulses into the brain so that my hand twitches. The amount of energy required to make my hand twitch is called the "motor threshold." Everyone has a different motor threshold, and the treatments are given at an energy level that is related to my individual

motor threshold. The motor threshold procedure takes about 20-30 minutes, and my doctor will determine how often it is re-evaluated or repeated.

g. Once the motor threshold is determined, the magnetic coil will be moved, and I will receive the treatment as a series of "pulses" lasting commonly around 5 seconds with a "rest" period of about 15-30 seconds between each pulse series. Treatment is to the front side of my head and will take about 40 minutes. I understand that this treatment does not involve any anesthesia or sedation and that I will remain awake and alert during the treatment. I will receive these treatments 5 times a week for approximately 4-6 weeks (20-30 treatments). My doctor will evaluate me at least weekly during this treatment course. The treatment is designed to relieve my current symptoms of depression. The doctor may modify these treatment parameters, such as adding additional treatments or stimulating a different place on my head, or the other side of my head.

h. During the treatment, I may experience tapping or painful sensations at the treatment site while the magnetic coil is turned on. These types of sensations were reported by about one-third of the patients who participated in the research studies. I may also experience muscle contractions around the site of stimulation. I may also experience tooth pain with stimulation. I understand that I should inform the doctor or staff if the sensation is painful. The doctor may then adjust the dose or make changes to the location where the coil is placed in order to help make the procedure more comfortable for me. I also understand that headaches were reported in half of the patients who participated in a recent clinical trial for a TMS device. I understand that both the discomfort and headaches got better over time in the research studies and that I may take common over-the-counter pain medications if a headache occurs.

i. The following risks are also involved with this treatment: TMS should not be administered to anyone who has magnetic-sensitive metal in their head or magnetic-sensitive metal within 12 inches of the TMS coil that cannot be removed. Failure to follow this restriction could result in serious injury or death. Objects that may have this kind of metal include:

- Aneurysm clips or coils
- Carotid or cerebral stents
- Implanted stimulators
- Electrodes to monitor your brain activity
- Ferromagnetic implants in your ears or eyes
- Bullet or shrapnel fragments
- Other metal devices or objects implanted in the head
- Pellets, bullets, or metallic fragments <12 inches from coil
- Magnetically activated dental implants
- Facial tattoos with metallic ink

j. There is no guarantee that this treatment will improve my condition as TMS is not effective for all patients with depression. Any signs or symptoms of worsening depression or unusual behavior or thoughts should be reported immediately to your doctor. You may want to ask a family member or caregiver to monitor your symptoms to help you spot any signs of worsening depression or unusual behavior.

k. Seizures (sometimes called convulsions or fits) have been reported with the use of TMS devices. There were no seizures in the NeuroStar clinical trials, which involved over 10,000 patient treatment sessions. In a recent large multi-center clinical trial, no seizures were observed with use of TMS for ~300 patients. However, seizures have occurred during other research and clinical use of TMS. Although the risk of having a seizure is quite low, complete medical information must be provided to your doctor so that your

level of risk can be assessed and discussed with you. The current estimated risk of seizure is 1 in 30,000 treatments (0.003%) or 1 in 1,000 patients (0.1%).

l. Because TMS produces a loud click with each magnetic pulse, I understand that I must wear earplugs or similar hearing protection devices with a rating of 30dB or higher of noise reduction during treatment. If I choose not to wear earplugs, I do so at my own risk.

m. I understand that most patients who benefit from TMS experience results by the sixth week of treatment. Some patients may experience results in less time, while others may take longer.

n. I understand that I may discontinue treatment at any time.

o. Off-label uses: The term "off-label" refers to the absence of FDA clearance or approval for a device or medication. Pharmaceutical companies and device manufacturers are not allowed to promote a product for any other purpose then what was studied in the FDA trials. However, once a drug or device has been approved for sale for one purpose, physicians are allowed to prescribe it for any other purpose that in their professional judgment is both safe and effective, and are not limited to FDA-approved indications. Commonly used off-label uses for TMS include extended protocols and/or bilateral treatments. You will be notified if off-label protocols are being used during your treatment.

p. Research: TMS Therapeutics would like permission to use anonymous data regarding treatment parameters and responses to treatment as part of research efforts to better understand how to maximize the use of TMS. This only applies to data generated during routine clinical care. If you are involved in any formal research projects, a separate consent will be included in that process. When the results of research are published or discussed in conferences, no information will be included that would reveal your identity. If you decide to take part in this type of study, you are free to withdraw at any time without giving a reason. This will not affect the relationship you have with the researcher or treatment provider. If you do not want data generated during your treatment used in this way, initial here _____.

I have read the information contained in this consent form about TMS and its potential risks. I have discussed it with Dr. _____ who has answered all of my questions. I understand there are other treatment options for my depression available to me including medications, psychotherapy, and other brain stimulation treatments like electroconvulsive therapy (ECT). These alternative treatment options were discussed with me.

I therefore permit Dr. _____ or staff to administer this treatment to me.

Patient's Printed Name	Patient's Signature	Date

Legal Representative Printed Name	Legal Representative's Signature	Date

*If signing as the legal representative, I represent to TMS Therapeutics that I am the legal representative of the patient and agree to provide proof of legal representation if requested. Should my legal authority terminate, I agree to provide written notification to TMS Therapeutics.

Clinician's Signature	Date