**TMS THERAPEUTICS IN SAN DIEGO, INC.**

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**Consent for 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, and any alternative treatments that are available if you decide not to be treated with TMS.

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 has been shown to relieve depressive symptoms in adults who have been treated with antidepressant medication given at a high enough dosage and for a long enough period but did not get better.

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

d. At the first session, a procedure will be done to establish the appropriate stimulation dose or “motor threshold” as well as determine the treatment location(s).

e. Once the motor threshold is determined, I will receive the treatment as a series of “pulses” lasting commonly around 4 seconds with a “rest” period of about 12-20 seconds. 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 approximately 5 times a week for approximately 4-6 weeks.

f. During the treatment, I may experience tapping or painful sensations at the treatment site. I may also experience muscle contractions around the site of stimulation. I may experience tooth pain or headaches during the treatment. I may take common over-the-counter pain medications a needed. 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.

g. 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. 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 • Implanted stimulators

• Carotid or cerebral stents • Pellets, bullets, or metallic fragments

• Facial tattoos with metallic ink • Magnetically activated dental implants

• Electrodes to monitor your brain activity

• Ferromagnetic implants in your ears or eyes

• Other metal devices or objects implanted in the head

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.

k. Seizures have been reported with the use of TMS devices. 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 can prescribe it for any other purpose that in their professional judgment is both safe and effective. 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. 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 understand there are other treatment options for depression available to me including medications, psychotherapy, and other brain stimulation treatments like electroconvulsive therapy.

TMS is being recommended for the treatment of: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Patient’s Signature Patient’s Printed Name Date

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Legal Representative’s Signature Legal Representative’s Printed Name 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.

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Clinician’s Signature Date