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**2027 Rev. TMS Consent Form

TMS Consent Form

Patient Consent for Transcranial Magnetic Stimulation (TMS Therapy)
Effective Date: November 2026

This version supersedes and replaces all prior versions of the Patient Consent for Transcranial Magnetic Stimulation (TMS Therapy).

This document provides information about Transcranial Magnetic Stimulation (TMS) Therapy, including the nature of the procedure, potential benefits, risks, side effects, treatment expectations, and available alternatives. Please read this document carefully and ask any questions before signing.

1. Scope and Duration of Consent

By signing this document, I voluntarily consent to receive Transcranial Magnetic Stimulation (TMS) Therapy at Blue Umbrella Psychiatry as prescribed by my treating provider.

I understand that this consent may apply to:

• My initial TMS treatment course, typically consisting of up to 36 sessions.

• Subsequent taper or maintenance treatments.

• Additional treatment courses or re-treatment when clinically appropriate.

• Clinically indicated adjustments to treatment frequency, duration, intensity, or other parameters based on my response and medical needs.

I understand that this consent is not limited to a specific calendar year and is intended to remain effective throughout my ongoing TMS care at Blue Umbrella Psychiatry unless withdrawn or superseded by updated consent.

I acknowledge that significant changes to my treatment plan, new risks, changes in my medical condition, or treatment protocols not previously discussed may require additional informed consent.

I understand that I may ask questions, request additional information, pause treatment, or withdraw my consent at any time.

2. Nature of the Procedure

a. Technology: TMS stands for Transcranial Magnetic Stimulation. It is a noninvasive medical procedure conducted using a Magstim device, which delivers pulsed magnetic fields through a treatment coil placed against the scalp. These magnetic pulses stimulate targeted areas of the brain involved in mood regulation.

b. FDA Clearance: TMS is an FDA-cleared treatment for certain conditions, including Major Depressive Disorder in eligible patients who have not achieved satisfactory improvement with prior antidepressant treatment. Specific indications and treatment protocols depend on the device's FDA-cleared labeling.
c. Treatment Experience: During treatment, a trained staff member will position the magnetic coil against my scalp. I will hear a clicking sound and may feel a tapping sensation. I will remain awake and alert during the procedure, and anesthesia is not typically required.
3. Treatment Protocol and Flexibility
a. Standard Treatment Course: A typical course of TMS Therapy for depression consists of approximately five treatments per week over several weeks, commonly involving up to 36 sessions, including any prescribed taper sessions.
b. Motor Threshold: Before treatment, my provider will determine my motor threshold, which is the stimulation intensity required to produce a measurable motor response, such as a hand or finger movement. I understand that my motor threshold may be reassessed periodically or when clinically indicated to maintain treatment safety and effectiveness.
c. Treatment Protocols: Depending on my clinical needs, my provider may recommend:
• Standard repetitive TMS (rTMS): Treatment sessions commonly lasting approximately 19 minutes for certain protocols.

• Intermittent Theta Burst Stimulation (iTBS): Shorter treatment protocols, commonly lasting approximately 3–9 minutes, depending on the prescribed protocol.

• Accelerated TMS: Treatment involving multiple sessions per day, when clinically appropriate.

• Maintenance or Re-treatment: Additional sessions or treatment courses based on my response and ongoing clinical needs.

I understand that treatment duration, frequency, and stimulation parameters may vary based on the prescribed protocol, clinical response, and medical judgment.
d. Off-Label Treatment: I understand that certain TMS protocols, treatment schedules, or indications may fall outside FDA-cleared labeling. This may include certain accelerated treatment protocols or treatment for conditions not specifically included in the device's FDA-cleared indications.
If off-label treatment is recommended, my provider will explain the proposed treatment, potential benefits, known risks, uncertainties, and available alternatives. I understand that additional informed consent may be required before beginning such treatment.
4. Risks and Potential Side Effects
I understand that TMS Therapy is generally well tolerated but, like any medical procedure, carries

potential risks and side effects.

a. Scalp Discomfort: I may experience tapping, pressure, discomfort, or pain at the treatment site. These sensations often decrease as treatment progresses. I agree to inform the treatment staff if discomfort becomes difficult to tolerate so that appropriate adjustments can be considered.

b. Headaches: I may experience headaches during or following treatment. These are generally temporary and may improve over time. My provider may recommend appropriate symptom management, including over-the-counter medication when medically appropriate.

c. Seizure Risk: Seizures are a rare but potentially serious risk associated with TMS Therapy. Although the risk is considered low when treatment is administered according to established safety guidelines, a seizure may occur during treatment.

Certain factors may increase seizure risk, including a history of seizures or epilepsy, neurological conditions, head injuries, certain medications, sleep deprivation, substance use, and other circumstances affecting seizure threshold.

I agree to notify my provider of any changes in my medical history, medications, sleep patterns, substance use, or other health conditions that could affect treatment safety.

I understand that my provider may reassess my motor threshold, modify my treatment protocol, postpone treatment, or discontinue TMS Therapy if medically necessary for my safety.

d. Hearing Protection: The TMS Therapy system produces a loud clicking sound during treatment, which may pose a risk of hearing discomfort or hearing changes. I understand that Blue Umbrella Psychiatry offers hearing protection, such as earplugs, to help reduce noise exposure during treatment. I acknowledge that the purpose and benefits of hearing protection have been explained to me, and I agree to notify the treatment team if I experience ringing in my ears, ear discomfort, or any changes in hearing.

e. Mood Changes: I understand that symptoms of depression may fluctuate during treatment and that some patients may experience worsening depression, increased anxiety, agitation, or other changes in mood.

I agree to promptly report significant changes in mood, worsening depression, suicidal thoughts, unusual mood elevation, or concerning behavioral changes.

I understand that family members or caregivers may help identify changes in symptoms or behavior during treatment.

f. Other Risks: Other uncommon or less well-established risks may exist. My provider will discuss any additional risks relevant to my medical history or prescribed treatment protocol.

5. Metal Implants and Medical Device Safety

I understand that the magnetic fields produced during TMS Therapy may interact with certain metallic objects or implanted medical devices.

The Magstim TMS system should not be used in patients with certain magnetic-sensitive metallic objects in or near the head, including within 12 inches (30 cm) of the treatment coil, as specified by the manufacturer's safety restrictions. Failure to follow these restrictions may result in serious injury.

Examples may include, but are not limited to:

• Cochlear implants.

• Certain aneurysm clips or coils.

• Brain stents.

• Electrodes used to monitor brain activity.

• Ferromagnetic implants in the ears or eyes.

• Bullet fragments or other metallic fragments.

• Other magnetic-sensitive devices or objects implanted in the head.

• Certain facial tattoos or permanent makeup containing metallic or magnetic-sensitive pigments.

Magnetic-Sensitive Metal Screening

☐ I do NOT have known magnetic-sensitive metal in or near my head.

☐ I DO have, or am unsure whether I have, magnetic-sensitive metal in or near my head and understand that additional evaluation is required before treatment.

Implanted Stimulators and Electronic Medical Devices

I understand that certain implanted stimulators and electronic medical devices may make TMS Therapy unsafe or inappropriate.

These may include:

• Deep brain stimulators.

• Cochlear implants.

• Vagus nerve stimulators.

• Pacemakers.

• Implantable cardioverter defibrillators.

• Wearable cardioverter defibrillators.

• Other implanted electronic medical devices.

I understand that patients with pacemakers, implantable cardioverter defibrillators, or other electronic devices require careful evaluation and that treatment may be contraindicated depending on the device and its location.

The Magstim TMS Therapy System should not be used by anyone who has:

1) Magnetic-sensitive metal in their head or within 12 inches (30 cm) of the magnetic coil that cannot be removed. Failure to follow this restriction could result in serious injury or death. These include but are not limited to: - Cochlear implants - Aneurysm clips or coils - Brain stents - Electrodes to monitor your brain activity - Ferromagnetic implants in your ears or eyes - Bullet fragments - Other metal devices or objects implanted in the head - Facial tattoos with metal ink or permanent makeup. *

- ☐ I do NOT have magnetic-sensitive metal in my head or near my head.
- ☐ I DO have magnetic-sensitive metal in my head or near my head, which may mean that I cannot do TMS therapy.

2) Implanted stimulators in or near the head. These may include: - Deep brain stimulators - Cochlear implants, - Vagus nerve stimulators. The Magstim TMS System should be used with caution in patients who have pacemakers or implantable cardioverter defibrillators (or are using wearable cardioverter defibrillators (WCD). Failure to follow this restriction could result in serious injury or death. *

- ☐ I do NOT have implanted stimulator in or near my head, and I do NOT have a pacemaker or implantable cardioverter defibrillators.
- ☐ I DO have implanted stimulator in or near my head, and/or I DO have a pacemaker or implantable cardioverter defibrillators, which means that I may not be able to do TMS therapy.

I agree to disclose all implants, metallic objects, electronic medical devices, and relevant surgical history before treatment.

I understand that my treating provider must evaluate any reported implant or medical device and determine whether treatment can safely proceed.

6. Expected Benefits and Treatment Outcomes

I understand that TMS Therapy is not effective for every patient and that results cannot be guaranteed.
Some patients notice improvement within the first several weeks of treatment, commonly around the fourth week, while others may experience improvement earlier or require additional time.
I understand that some patients may experience limited improvement or no meaningful response.
Potential benefits may include reduced depressive symptoms, improved daily functioning, and improved quality of life. However, individual results vary.
I understand that symptoms may temporarily fluctuate during treatment and that any significant worsening of depression, anxiety, or other symptoms should be reported promptly to my provider.
7. Long-Term Results and Maintenance Treatment
I understand that the benefits of TMS Therapy vary from patient to patient and that improvement in symptoms may not be permanent. Some patients experience sustained improvement, while others may experience a return of symptoms over time.
I understand that my provider may recommend continued medication management, psychotherapy, maintenance TMS sessions, or additional treatment courses based on my individual needs and clinical response.
I acknowledge that there is no guarantee of permanent symptom relief and that ongoing follow-up care may be recommended to help maintain treatment benefits.
8. Alternative Treatment Options
I understand that other treatment options may be available depending on my condition, including:
• Psychiatric medication management.

• Individual or group psychotherapy.

• Other medically appropriate treatments or interventions.

• Continued monitoring or alternative treatment approaches recommended by my provider.

I understand that these alternatives may have their own potential benefits, risks, and limitations.
I acknowledge that I have had the opportunity to discuss alternative treatment options with my provider and understand that I am not required to undergo TMS Therapy.
9. Insurance Coverage and Self-Pay Options
I understand that insurance coverage for TMS Therapy depends on my individual insurance plan, medical necessity requirements, authorization criteria, and the specific treatment being provided.
I acknowledge that certain treatments, including additional sessions, maintenance therapy, accelerated protocols, or off-label treatments, may not be covered by insurance.
Blue Umbrella Psychiatry will make reasonable efforts to obtain insurance authorization when applicable; however, authorization or verification of benefits does not guarantee payment by my insurance company.
If treatment is not covered or authorized by my insurance, available self-pay options, associated fees, and financial responsibilities will be discussed with me before proceeding with treatment.

I understand that agreeing to this medical consent does not automatically authorize additional self-pay charges and that any applicable financial arrangements will be addressed separately.

10. Patient Responsibilities and Ongoing Safety

To support safe and effective treatment, I agree to:

• Provide an accurate and complete medical history.

• Inform the treatment team of medication changes, new diagnoses, hospitalizations, or changes in my health.

• Report changes in sleep, substance use, seizure history, or other factors that may affect treatment safety.

• Follow the treatment team's safety instructions, including applicable hearing protection requirements.

• Inform staff of any discomfort, unusual symptoms, or concerns during treatment.

• Participate in recommended clinical follow-up and reassessment.

• Communicate any worsening symptoms or changes in my mental health.

I understand that my provider may modify, postpone, or discontinue treatment if necessary for my safety.

11. Right to Withdraw Consent

I understand that participation in TMS Therapy is voluntary.

I may ask questions, request additional information, pause treatment, or withdraw my consent at any time.

I understand that withdrawing consent will not prevent me from receiving other appropriate medical care at Blue Umbrella Psychiatry.

12. Patient Acknowledgment and Authorization

By signing below, I acknowledge and agree that:

• I have read and understand the information contained in this TMS Therapy Informed Consent Form.

• The nature of the procedure, potential benefits, risks, side effects, and available alternatives have been explained to me.

• I have had the opportunity to ask questions and receive answers.

• I understand that treatment outcomes cannot be guaranteed.

• I understand that my treatment plan may be adjusted based on my clinical response and medical needs.

• I understand that significant changes in my treatment or medical circumstances may require additional discussion or updated informed consent.

• I understand that this consent is not limited to a specific calendar year and is intended to remain effective for my ongoing TMS care unless withdrawn or superseded.

• I understand that I may withdraw my consent or discontinue treatment at any time.

As an option for patients requiring more than the 36 sessions typically approved by insurance, we will make efforts to seek authorization for additional treatments. However, if insurance does not approve further sessions, we offer the option to purchase additional TMS sessions in packets of 5 at a total cost of $250.

I have read this guide and discussed my questions with the doctor, Nurse Practitioner, or TMS technician. I understand that my treatment plan is dynamic and that changes to my specific protocol (time, frequency, or intensity) will be communicated to me by my provider but do not require a new signature for each adjustment during the 2026 year. I retain the right to revoke this consent or pause treatment at any time.Therefore, I permit Dr. Eric Robbins MD and his TMS Therapy staff at Blue Umbrella Psychiatry to administer TMS therapy treatment to me.

PATIENT SIGNATURE *

Date: *