

Transcranial Magnetic Stimulation Adult Safety Screen

(Please circle)

1.	Have you ever had an adverse reaction to TMS?	Yes	No	
2.	Have you ever had a seizure?	Yes	No	
3.	Have you ever had an EEG?	Yes	No	
4.	Have you ever had a stroke?	Yes	No	
5.	Have you ever had a head injury (including neurosurgery)?	Yes	No	
6.	Do you have any implanted devices such as cardiac pacemakers, medical pumps, or intracardiac lines?	Yes	No	
7.	Do you suffer from frequent or severe headaches?	Yes	No	
8.	Do you have any metal in your head (outside of your mouth) such as shrapnel, surgical clips, or fragments from welding or metalwork?	Yes	No	
9.	Have you ever had any other brain-related condition?	Yes	No	
10.	Have you ever had any illness that caused brain injury?	Yes	No	
11.	Are you taking any medications?	Yes	No	
12.	Have you ever fainted?	Yes	No	
13.	Do you experience tinnitus (ringing in your ears)?	Yes	No	
14.	Have you ever had any problems while undergoing an MRI scan?	Yes	No	
15.	Has anyone in your family ever had a seizure or have epilepsy?	Yes	No	
16.	If you are a woman of child-bearing age and are sexually active, are you <i>not</i> using a reliable method of birth control?	Yes	No	N/A
17.	If you are a woman of child-bearing age, are you pregnant?	Yes	No	N/A
18.	Do you need further explanation of TMS and its associated risks?	Yes	No	
If any item was marked 'yes,' please explain here:				

Patient Signature _____ Date _____

Patient Name _____

Transcranial Magnetic Stimulation (TMS) Therapy INFORMED PROCEDURAL CONSENT

My doctor has recommended that I receive treatment with repetitive transcranial magnetic stimulation (TMS). I am reviewing this consent prior to starting therapy so that I will understand TMS treatment and its potential risks and benefits.

GENERAL INFORMATION

TMS stands for transcranial magnetic stimulation. TMS is a non-invasive FDA approved medical procedure used to help treat depression. TMS treatment uses a small device called a "treatment coil" placed over the scalp to deliver brief magnetic fields to stimulate the brain. These magnetic fields are the same type and strength as those used in magnetic resonance imaging (MRI) machines. The TMS pulses stimulate the brain without surgery, anesthesia or sedation. Patients remain awake and alert and may return to work or daily routines following each treatment.

The TMS pulses generate a weak electrical current in the brain that briefly activates neural circuits at the stimulation site. TMS has been shown to be a safe and well-tolerated procedure that can be an effective treatment for adult patients with depression who have not benefitted from antidepressant medications.

The potential benefit of TMS is that it may lead to improvements in my depressive symptoms. I understand that not all patients respond equally well to TMS. Like all forms of medical treatment, some patients improved quickly, others improve and later relapse, while others may fail to have any response to TMS.

Some medications/substances increase the risk of seizure during TMS. If I am taking any medications/substances that may increase my risk of seizure, your TMS physician may discuss with you the need to be taken off or reduce the dose of these medications before starting TMS.

ALTERNATIVES TO TMS

I understand there are alternative treatment options for my condition(s), including medications, psychotherapy, and electroconvulsive therapy (ECT). My TMS doctor has explained why TMS has been recommended for my specific case.

PRECEDURE

TMS therapy involves a series of outpatient treatments. The TMS equipment consists of computer console with a "coil" attached. The coil is a collection of wires wrapped in a plastic case. This coil is not magnetic when there is no electricity going through it. When the machine sends electricity through the coil, a powerful but temporary magnetic field is created. This magnetic field can travel through skull and bone. During TMS sessions, I will sit in a comfortable chair next to the console with the coil positioned on my head.

Prior to the start of each session, my TMS Treater will ask several questions relevant to my TMS treatment. It is important that I give accurate and complete information, including past and present drug use, to avoid potential serious consequences to my well-being.

- I will be asked about any medical or psychiatric changes since my last visit.
- I will be asked about the occurrence of any side effects or adverse events.
- I will be asked about any changes in either prescription or over-the-counter medications (including herbal supplements). I understand I can continue my medicines while I am receiving TMS. If there have

been changes to medications or if I take them not as prescribed prior to a TMS session, the TMS Treater may choose to reschedule the session due to safety-related concerns.

- I will be asked about any alcohol or other substances I may have consumed since my last visit. To ensure my safety during TMS, I may be asked to provide a urine sample and/or test for alcohol. If the TMS treatment team has concerns about my safe use of substances my TMS session may be postponed and the test results may be disclosed to my primary mental health provider.
- I will be asked about my hours of sleep prior to each treatment session. Because sleep is frequently disrupted when people are depressed and amount of sleep affects seizure risk, my TMS session may need to be rescheduled if my sleep has been inadequate.
- At the end of every 5 treatment sessions, I will be asked to complete psychological self-assessments about my mood, including thoughts of suicide. This is required to monitor my progress throughout my TMS treatment.

FIRST TREATMENT VISIT (~1hr)

A psychiatrist specializing in TMS will determine the dosage and location appropriate for me. The amount of energy required to make my thumb twitch is called my "motor threshold." To determine this amount of energy (dosage), the location of my motor cortex will be determined, and various doses of stimulation will be tested. This procedure requires placing the treatment coil gently on my scalp over the part of the brain (motor cortex) that moves my thumb muscles when stimulated. I will hear a clicking sound and feel a tapping sensation on my scalp when the coil is delivering the magnetic pulses. Everyone has a different motor threshold. This procedure takes approximately 20-30 minutes and is typically only performed during the initial visit.

Once my motor threshold is determined, the magnetic coil will be moved to the front side of my head over a region of the brain believed to influence depression. TMS is then delivered over a span of 3 minutes. I may ask to stop the procedure at any time. I will be awake and alert during the entire procedure.

SUBSEQUENT TREATMENT VISITS (~15-30min)

Each treatment session consists of magnetic pulses at my therapeutic dosage over 3 minutes as prescribed by my TMS physician. A TMS staff member will monitor me during the entire treatment. I will be instructed to remove any metal/magnetic sensitive objects near the magnetic coil. I will be offered earplugs for my comfort and safety. A treatment head cap identifying my location for the treatment coil will be placed on my head. The coil will then be gently placed over the identified treatment location. I will be awake and alert during the entire procedure. There are no activity restrictions after treatment is completed. During my course of TMS I will continue my regularly scheduled appointments with my psychiatrist, who will continue prescribe my medications.

NUMBER OF TREATMENTS

A TMS treatment course is usually 36 sessions: 5 sessions per week (Mon-Fri) over 6 weeks followed by 6 taper sessions over a 3-week period. The total number of treatments I will receive can vary and depends on my psychiatric condition, my participation in my therapy, my responses to treatment, and the medical judgment of my TMS psychiatrist/mental health team. Patients who respond to TMS typically experience some improvement within 3-4 weeks. However, some patients may experience results in less time while

others may take longer to achieve maximum response. I may choose to end my treatments at any time but it is strongly suggested that I discuss this decision with my TMS doctor and my mental health team.

RISKS

TMS is generally well tolerated and very few side effects are known to occur although, as with any medical treatment, there is risk of side effects. No known immediate or long-term adverse cognitive (thinking/memory) effects are associated with TMS. Only a small percentage of patients discontinue treatment because the following side effects:

- Mild scalp discomfort: facial twitching or uncomfortable sensations at the treatment site during treatment; reported by approximately 30% of patients. Inform staff if this occurs; adjustments to stimulation settings or coil placement may increase comfort. About 10% of patients report mild site discomfort following TMS treatments.
- Mild to moderate headache: experienced by about 15% of patients; tends to lessen or go away over treatment time. Headaches and site discomfort generally respond well to over-the-counter pain medications (acetaminophen or ibuprofen). Inform staff if this occurs; adjustments to stimulation settings or coil placement may increase comfort.
- Mild facial pain: small risk of dental or sinus pain during or immediately after TMS treatments. Inform staff if this occurs; adjustments to stimulation settings or coil placement may increase comfort.
- Hearing loss or tinnitus: TMS device produces a moderately loud click with each pulse. There have been no reported cases of permanent hearing loss with properly functioning hearing protection. Wearing earplugs during treatment minimizes the risk of hearing loss. If earplugs become loose or fall out, notify treatment staff immediately.
- Unusual increased energy/rapid racing thoughts: there is a small risk for the emergence of hypomania with TMS. Some people may feel no need for sleep or have higher-than-normal energy levels. Inform staff immediately; TMS session may need to be postponed a day or two.
- Worsening depression/Suicidal thinking: a major risk in treating seriously depressed patients. TMS is *not* thought to cause suicidal thinking. The concern is that many depressed people think of suicide. I will frequently be asked about suicidal thoughts during my course of TMS. I will provide honest and open answers to such questions and my treatment team will try to help me work through such feelings. If I have any suicidal thoughts I will seek appropriate care immediately from my mental health team. I may want to ask my family/friends to monitor my symptoms to help me spot any signs of worsening depression.
- Pregnancy: TMS may be an option in pregnant women where non-invasive, non-systemic treatment for depression during pregnancy is preferred or indicated.
- Seizure during treatment: most serious known risk of TMS; only a very few cases of seizure reported (less than 0.1 % per treatment course). In fact, seizure risk with TMS is no greater than what

has been observed with antidepressant medications. All reported TMS seizures have resolved promptly on their own; none have had any lasting effects or adverse impact. Having a seizure disorder, substance use, or having changed medications may influence the risk of seizure with TMS. The TMS team follows up-to-date safety guidelines designed to minimize the risk of seizures.

In the unlikely event a seizure does occur, I will be closely monitored and treated for any medical or psychological consequences. If needed, EMS will be called. If I have no other medical or neurological problem that caused the seizure, a progress note in my medical record will indicate that the seizure during TMS does not increase my risk for future seizures.

My TMS treatment team has informed me of these signs/symptoms of potential risks of TMS. My TMS treatment team will monitor me for the development of these side effects. If I notice any of these signs/symptoms, I will alert my TMS treatment team immediately.

LONG-TERM ADVERSE EFFECTS

There are no known long-term adverse effects reported with the use of TMS.

TMS TREATMENT ELIGIBILITY

To ensure my safety, the following criteria are required before receiving TMS:

- I have a current diagnosis of treatment-resistant depression
- If I have any previous history of traumatic brain injury, stroke, epilepsy/seizures, or neurological disorders, I have discussed it with my TMS care team
- I have no metal in my head that may be affected by magnetic fields, such as:
 - o Shrapnel or bullet fragments
 - o Facial tattoos with metallic or magnetic sensitive ink
 - o Metallic implants in my eyes or ears (including cochlear implants)
 - o Aneurysm clips or coils
 - o Stents/shunts in neck or brain (including cerebral spinal fluid shunts)
 - o Implanted stimulators (vagus nerve stimulator, deep brain stimulator)
 - o Cardiac pacemakers, stents, or implantable devices
 - o Cardioverter defibrillator (ICD)
 - o Electrodes to monitor my brain activity (including EEG)
 - o Metal devices or objects implanted in or near my head
 - o Magnetically activated dental implants (most dental work is safe)
 - o Staples/sutures

ACKNOWLEDGEMENTS

- I understand that my decision to agree to TMS is made on a voluntary basis and that I may withdraw my consent and have treatments stopped at any time.
- I understand that I am responsible for all co-payments
- I will keep my TMS appointments on a timely and regular basis to the best of my ability. If it is necessary to miss an appointment, I will notify the TMS Treater as soon as I know I will miss the appointment.
- I authorize and request that emergency treatment be performed if a situation arises which, in the best judgment of the medical staff, requires emergency care.
- I understand that I am free to ask at any time for further details, explanations, and questions about TMS.

CONFIDENTIALITY AND PRIVACY

I have read and agreed to the Privacy Notice provided to me. I understand that I can obtain a printed copy and can ask for clarification on any policies stated in it.

AUTHORIZED CONSENT

By signing this document I agree to the following statements:

A psychiatrist specializing in TMS has reviewed my medical record, discussed the risks and benefits of TMS, explained potential problems and contraindications to TMS, identified the likelihood of success and treatment alternatives, and determined my appropriateness for TMS treatment. I understand that a positive outcome cannot be guaranteed and are based on my compliance with treatments.

I have carefully read and understand the information contained in this consent. All of my questions have been answered. I authorize and request to begin TMS treatment sessions.

Signature of Patient	Printed Name	Date
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Signature of Healthcare Provider	Printed Name	Date
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Securing Consent

Signature of Witness	Printed Name	Date
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FINANCIAL POLICY AND AUTHORIZATION

Tricounty Behavioral Health (TCBH) makes every attempt to obtain Pre-Authorization for TMS treatment with your primary insurance carrier, however, patients often have copays and deductibles. Additionally, Pre-Authorization does not always guarantee coverage. In these cases, the patient is ultimately responsible for payment.

- TCBH requires payment at time of service. Total out-of-pocket costs are estimated prior to starting treatment based on your benefits and pre-authorization obtained from your insurance carrier.
 - The patient is responsible for all copays and deductibles. The total amount will be divided over the number of treatments and can be paid at each treatment session.
 - Any unpaid claim billed to insurance will be the responsibility of the patient.
- The patient is responsible for all costs of their treatment and will also be responsible for any costs incurred regarding bill collection. Payment may be made by cash or credit card. We do not accept personal or 3rd party checks.
- Duration of treatment is based on treatment plan set by the TMS physician, which may differ from the referring physician.
- If you are unable to come to an appointment for any reason you must cancel your appointment at least 24 hours in advance. Cancellations are billed at \$75.00 if you cancel with less than 24 hours notice. Insurance does not cover missed appointment fees. Failure to receive a reminder does not waive this cancellation fee. You are responsible to remember your appointment date(s) and time(s).
- If you are 18 years of age or older, unless other signatures are provided, financial responsibility will default to you.
- Past due balances: unpaid balances of 30 days past due may be subject to be submitted for collections. If balances are not paid, we reserve the right to utilize collection agency services. Payments are expected at the time of service, however, all balances are due within 30 days.
- It is the responsibility of the patient to notify TCBH of any changes in insurance.

I hereby acknowledge that I have read, understand, and agree to this Financial Policy. By signing this form, I acknowledge that my insurance coverage, notification of pre-authorization requirements, and terms of coverage are ultimately my responsibility. If pre-authorization is obtained but your insurance provider rejects services you may still be responsible for payment of services provided.

Patient Signature

Date

Patient Printed Name

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: _____

DATE: _____

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3

add columns + +

(Healthcare professional: For interpretation of TOTAL, TOTAL:
please refer to accompanying scoring card).

<p>10. If you checked off <i>any problems</i>, how <i>difficult</i> have these problems made it for you to do your work, take care of things at home, or get along with other people?</p>	<p>Not difficult at all _____</p> <p>Somewhat difficult _____</p> <p>Very difficult _____</p> <p>Extremely difficult _____</p>
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PHQ-9 Patient Depression Questionnaire

For initial diagnosis:

1. Patient completes PHQ-9 Quick Depression Assessment.
2. If there are at least 4 ✓s in the shaded section (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.

Consider Major Depressive Disorder

- if there are at least 5 ✓s in the shaded section (one of which corresponds to Question #1 or #2)

Consider Other Depressive Disorder

- if there are 2-4 ✓s in the shaded section (one of which corresponds to Question #1 or #2)

Note: Since the questionnaire relies on patient self-report, all responses should be verified by the clinician, and a definitive diagnosis is made on clinical grounds taking into account how well the patient understood the questionnaire, as well as other relevant information from the patient.

Diagnoses of Major Depressive Disorder or Other Depressive Disorder also require impairment of social, occupational, or other important areas of functioning (Question #10) and ruling out normal bereavement, a history of a Manic Episode (Bipolar Disorder), and a physical disorder, medication, or other drug as the biological cause of the depressive symptoms.

To monitor severity over time for newly diagnosed patients or patients in current treatment for depression:

1. Patients may complete questionnaires at baseline and at regular intervals (eg, every 2 weeks) at home and bring them in at their next appointment for scoring or they may complete the questionnaire during each scheduled appointment.
2. Add up ✓s by column. For every ✓: Several days = 1 More than half the days = 2 Nearly every day = 3
3. Add together column scores to get a TOTAL score.
4. Refer to the accompanying **PHQ-9 Scoring Box** to interpret the TOTAL score.
5. Results may be included in patient files to assist you in setting up a treatment goal, determining degree of response, as well as guiding treatment intervention.

Scoring: add up all checked boxes on PHQ-9

For every ✓ Not at all = 0; Several days = 1;
More than half the days = 2; Nearly every day = 3

Interpretation of Total Score

Total Score	Depression Severity
1-4	Minimal depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

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