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Uptown Psych

Patient Consent Form for Transcranial Magnetic Stimulation (TMS)

This is a Patient Consent for a medical procedure called Transcranial Magnetic Stimulation (TMS). This consent outlines the treatment that my Attending Psychiatric Physician has prescribed for me, the risks of this treatment, the potential benefits of this treatment to me, and any alternative treatments that are available for me if I decide not to be treated with TMS.

My Attending Psychiatric Physician has told me that I have the following condition(s):

- ☐ Treatment-Resistant Depression (Major Depressive Disorder)
- ☐ Post-Traumatic Stress Disorder (PTSD)
- ☐ Auditory Hallucinations
- ☐ Obsessive-Compulsive Disorder
- ☐ Bipolar Disorder (Depressive phase)
- ☐ Tinnitus
- ☐ Cognitive Impairment (Mild Cognitive Decline)
- ☐ Attention-Deficit/Hyperactivity Disorder (ADHD)
- ☐ Fibromyalgia
- ☐ Neuropathic Pain
- ☐ Other: eg Stroke rehabilitation,Parkinson's etc.._____

My Attending Psychiatric Physician has explained to me that:

1. A TMS treatment session is performed with an FDA cleared system that delivers pulsed magnetic stimulations over my scalp. The magnetic fields are of a similar in strength as those used in diagnostic magnetic resonance imaging (MRI) machines.

2. TMS has been shown to be a safe and effective treatment for patients with depression.

3. TMS was shown to reduce depressive symptoms in adults who have had partial success or failed treatment with other modalities. I understand that my treatment may include off-label use of TMS. Off-label device uses (OLDU): 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. Pain, headache, migraine, and OCD protocols, etc... You will be notified if off-label protocols are being used during your treatment.

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4. At this time, the FDA approved indication for TMS does not include Maintenance sessions, I am also aware that this is not covered by my insurance (Medicare), hence, I'll be paying for it privately. The treatment would be administered by the Silicon Valley TMS staff and I'll be monitored by them as well during each session.

5. A provocation induction may be administered depending on what type of treatment you and your attending Physician decide upon. The goal of the provocations is to induce the patient's with a moderate degree of obsessive-compulsive distress\urge immediately before initiating dTMS. The provocations are separated into internal and external provocations. The internal provocations are mainly questions related to thoughts, images or impulses that usually trigger the urge to perform compulsive behaviors. External provocations typically involve requesting the patient to perform an actual act (e.g., touching, praying, etc.) that will increase distress.

6. During a TMS treatment session, my Attending Psychiatric Physician or a qualified member of the clinic staff will place the magnetic coil against my scalp on the designated region of my head. The magnetic field produced by the device is targeted over areas my Attending Psychiatric Physician believes may be affected in my condition.

7. My Attending Psychiatric Physician or a qualified member of the clinic staff will position my head, then, a procedure will be done to find the accurate stimulation dose. The magnetic coil will be placed on an area of my head my doctor has chosen, and I will hear a clicking sound and feel a sensation on my scalp. In my initial visit, my Attending Psychiatric Physician or a qualified member of the clinic staff will adjust the device to give just enough energy stimulation into the brain so that we can elicit a hand twitch (sometimes thumb and index finger twitching). The amount of energy needed is called the "motor threshold." (MT) Everyone has a different MT, and the treatments are individualized.

8. During Treatment the magnetic coil will be placed in the designated area for treatment that has been decided by the treatment team, and I will receive the treatment as a series of "pulses" for 1-5 seconds every 1-26 seconds (depending on the protocol used), other protocols may be used (which the team will explain to me). Treatment is usually to the left front side of my head (sometimes right) in an area designated as the Dorsolateral prefrontal cortex (DLPFC) and will take between ~18-20 minutes. I will initially receive these treatments 5 times a week for approximately 4-6 weeks (20-30 treatments) unless I am told otherwise. My Attending Psychiatric Physician (or designee) will evaluate me about every week during this treatment course alongside the rest of the treatment team, he/she will also be getting daily reports of my treatment. My Attending Psychiatric Physician may change the treatment settings, add additional treatments or stimulate a different location in my head (in that case it will always be explained to me as to the reasoning and the plan).

9. During the treatment, there is a slight chance that I may experience 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. I will inform my Attending Psychiatric Physician or a qualified member of the clinic staff if the sensation is uncomfortable or painful. My Attending Psychiatric Physician or a qualified

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member of the clinic staff may then adjust the dose or change the location of the coil to make the procedure more comfortable. I understand that discomfort and headaches usually get better quickly and that I can take over-the-counter pain medications if a headache occurs. We have made some modifications and our protocols to minimize the discomfort. Our goal is to make you comfortable and to have successful outcomes.

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. Objects that may have this kind of metal include: Please initial each to attest that I do not have any of the following:
    - ❏ Aneurysm clips or coils
    - ❏ Implanted stimulator or pacemaker
    - ❏ Electrodes to monitor my brain activity
    - ❏ Bullet or shrapnel fragments
    - ☐ Pellets, bullets, or metallic fragments
    - ☐ Other metal devices or objects implanted in the head
    - ☐ Magnetic implants in my ears or eyes
    - ☐ Magnetically active dental implants
11. My Attending Psychiatric Physician or a qualified member of the clinic staff will do their best to move the coil carefully over my head, although rare, I understand that there is a chance of getting hit in my head by the magnet during positioning (this occurred 2 times in one year during 4,000 treatments).

12. There is <u>no guarantee</u> that this treatment will improve my condition, TMS is not effective for every patient. I will tell my Attending Psychiatric Physician or a qualified member of the clinic staff right away if I have any worsening depression or unusual behavior.

13. <u>Seizures</u> (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 low, but I will give my Attending Psychiatric Physician or a qualified member of the clinic staff complete medical information so that my 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%).

14. I understand that I can stop the treatment at any time, however, I will take the responsibility of informing the treatment team if I decide to do that and my reasoning.

15. If I am paying out of pocket for the treatment, I understand that the fee for the first treatment (including treatment calibration) is _____ and for the following treatments the fee is _____. (you may want to check with the office manager if you are eligible for any discounts).

16. I have read the information contained in this consent form about TMS and its potential risks. I have discussed it with my Attending Psychiatric Physician who has answered all of my questions. I understand there are other treatment options for my condition including medications, psychotherapy, and other kinds of brain stimulation

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like electroconvulsive therapy (ECT). These alternative treatment options were discussed with me and I have chosen TMS.

17. I promise to inform the Doctor or assistant if I experience anything uncomfortable, during or after the stimulation even if I think that it is not caused by the stimulation. This is not optional, it is an obligation.

We aim to provide the best care possible for you with the least side effects.
Thank you for the honor and the privilege.

I request and allow my Attending Psychiatric Physician and/or a qualified member of the clinic's staff to administer this treatment to me.

Patient Printed Name (if a minor than an adult guardian is needed)	Patient Signature	Date

Witness Printed Name	Witness Signature	Date