Aspen COUNSELING & Consulting, L.L.C.

New directions in emotional health and wellbeing

# Patient Consent for a Medical Procedure

## BrainsWay Deep TMS Therapy

This is a patient consent for a medical procedure called BrainsWay Deep TMS® (dTMS). 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 BrainsWay Deep TMS. Once you have reviewed this consent form, be sure to ask your doctor about any additional questions that you may have about BrainsWay Deep TMS.

Dr. Thomas Wright/Dr. Raymond Garcia have explained the following information to me:

a. TMS stands for "Transcranial Magnetic Stimulation." BrainsWay Deep TMS is a medical procedure. A TMS treatment session is conducted using a device called the BrainsWay Deep TMS System, which provides electrical energy to a "treatment coil" or magnet that delivers pulsed magnetic fields. These magnetic fields are the same type and strength as those used in magnetic resonance imaging (MRI) machines.

b. Deep TMS is a non-invasive, non-systemic, FDA cleared treatment for patients suffering from Major Depressive Disorder who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode. The FDA clearance was obtained following BrainsWay's completion of a multicenter study in the US and abroad which was conducted to investigate the safety and efficacy of the Deep TMS treatment.

c. During a TMS treatment session, the doctor or a technician will place a treatment cap on my head, after which the treatment helmet containing the magnetic coil will be applied. The magnetic fields that are produced by the magnetic coil are pointed at a region of the brain that is thought to be responsible for causing depression.

d. At the first session to begin treatment, the doctor or a member of their staff will place a treatment cap on my head, and the helmet coil will stimulate the brain's primary motor cortex with a series of pulses to produce a motor response, or a "twitch", in my right hand. This will determine the precise treatment location. Next, the doctor will again produce this motor response to determine my "motor threshold" (MT), or the amount of energy required to make my hand twitch. Each individual has a different motor threshold, and my treatments will be given at an energy level that is just above my individual motor threshold. My doctor may need to re-evaluate my motor threshold if my condition changes significantly while receiving my treatment.

e. Once motor threshold is determined, the helmet coil will be moved to the correct treatment location, and I will receive the treatment as a series of "pulses" that last 2 seconds, with a rest period of 20 seconds between each pulse sequence for a total of 1,980 pulses. Treatment is targeted to the region of

the brain called the dorsolateral prefrontal cortex (DLPFC). Each treatment session lasts approximately 20 minutes. The dTMS treatment does not involve any anesthesia or sedation and that I will remain awake and alert during the treatment.

I will receive these treatments at least 5 times per/week for 4 to 6 weeks (20 to 30 treatments). I will be evaluated as needed by Dr. Thomas Wright / Dr. Raymond Garcia during this treatment course.

f. I understand that most patients who benefit from BrainsWay Deep TMS Therapy experience results by the third or fourth week of treatment. Some patients may experience results in less time while others may take longer.

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

## SAFETY AND RISK INFORMATION

The safety of the BrainsWay Deep TMS System was demonstrated in a clinical study involving 233 patients with moderate to severe Major Depressive Disorder. However, like other medical procedures and forms of treatment, BrainsWay Deep TMS involves some risks and adverse events.

a. Seizures (sometimes called convulsions or fits) have been reported with the use of TMS devices. I understand that I must discuss with my doctor if I have consumed or intend to consume alcohol/drugs prior to treatment. I understand that I must discuss with my doctor if I have a history or family history of seizure/epilepsy or potential alteration in seizure threshold. This includes stroke, head/ brain injury, change in medication, change in electrolyte balance, high intracranial pressure, severe headaches or presence of other neurologic disease that may be associated with an altered seizure threshold, or concurrent medication or other drugs that are known to lower the seizure threshold, secondary conditions that may significantly alter electrolyte balance or lower seizure threshold, or where a quantifiable motor threshold cannot be accurately determined.

b. Headaches were reported in 47% of the subjects participating in the clinical study. However, 36% of patients who had received a placebo treatment instead of Deep TMS also reported headaches, indicating that the headaches reported by Deep TMS patients were not necessarily caused by the Deep TMS treatment. Headaches usually get better or go away completely with successive treatments. Additionally, headaches may be relieved by over-the-counter medicine such as acetaminophen or Ibuprofen. I understand that I should inform my doctor if this occurs.

c. Application site pain and discomfort was reported in 25% and 20%, respectively, of those participating of the subjects participating in the clinical study.

I understand that I should inform the treatment administrator if I feel pain or discomfort during the treatment. The Deep TMS helmet may be slightly adjusted on the head to relieve the pain or discomfort. Pain and discomfort associated with treatment usually gets better or goes away altogether with successive treatments.

d. Other side effects which may occur include pain in jaw, muscle twitching, back pain, anxiety and insomnia. I understand that I should inform my doctor if I experience any of these adverse events.

e. If I am currently on antidepressant medications, my doctor may taper down my dosage prior to and during the course of Deep TMS treatment. Because BrainsWay Deep TMS may take a few weeks before symptom improvement occurs, in the meantime my depression may worsen and increased mood instability and thoughts of suicide could occur. I understand that if I experience these symptoms, my doctor should be notified immediately.

f. I understand that Deep TMS should not be used by patients with metal implants and other metal substances in or around their heads, except for standard amalgam dental fillings. Examples of restricted metal substances include bullet fragments, stents, aneurism clips/coils, implanted stimulators, brain monitoring electrodes, ear/eye ferromagnetic implants, metal ink in facial/head tattoos and permanent makeup. I understand that failure to follow this restriction could result in serious injury or death.

g. During treatment with the BrainsWay Deep TMS System a loud clicking sound is emitted. Therefore, patients must use earplugs with a rating of at least 30 dB of noise reduction. There have been no reports of hearing loss with the Deep TMS Treatment in the clinical study when earplugs were used.

## ALTERNATE TREATMENT OPTIONS

I understand that dTMS is currently only FDA approved for the treatment of major depressive disorder in patients that have failed to respond to prior medication treatments. If I elect to utilize this procedure for an "off-label" treatment protocol, or anything other than what it is indicated by the FDA, I hereby waive any liability to Aspen Counseling & Consulting staff or Dr. Wright/Dr. Garcia should I not receive benefit from the treatment.

1. 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 for associated symptoms of anxiety. You will be notified if off-label protocols are being used during your treatment.

While my doctor has recommended BrainsWay Deep TMS for me, I understand that a variety of other treatment options for depression exist which may be suitable for me. These might include: Psychotherapy, Medication, or Electro-Convulsive Therapy (ECT). Which treatment option is right for me depends on a variety of factors including but not limited to previous experience, severity of my disorder, potential side effects and other factors and risks.

I understand that BrainsWay Deep TMS is not effective for all patients with depression. I will report any signs or symptoms of worsening depression immediately to my doctor. I understand that it is advisable to have a family member or caregiver monitor any symptoms and to assist in spotting any signs of worsening depression.

## PATIENT VERIFICATION

I have read the information contained in this Medical Procedure Consent Form about BrainsWay Deep TMS Therapy and its potential risks. I have discussed them with Dr. Thomas Wright/Dr. Raymond Garcia, and they have answered all of my questions. I understand there are other treatment options for my depression available to me and this has also been discussed with me. I also understand that I may discontinue treatment at any time.

I agree and acknowledge that I am under no pressure or duress to sign this Consent Form and that I have been given a reasonable opportunity to review it before signing.

I therefore permit Dr. Thomas Wright/Dr. Raymond Garcia and his staff to administer this treatment to me.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| PATIENT | DATE | WITNESS | DATE |

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# Electronic Device Waiver

I, _____, hereby release Aspen Counseling and Consulting staff from liability for any damage incurred to any electronic device that I may choose to use during my TMS treatment session. I understand that Transcranial Magnetic Stimulation (TMS) treatment involves the use of magnetic coils which, when placed to closely to electronic devices such as cellular phones, iPods, or MP3 players, may cause damage or erasure of information on the device. I acknowledge having been adequately informed about the risk associated with this and I hereby waive any liability against Aspen Counseling and Consulting.

_____ _____

Patient Signature Date

_____ _____

Witness Signature Date