Pacific Center for Neurostimulation

Deep TMS Treatment- Consent Form

Name of Physician: _____

Name of Clinic: Pacific Center for Neurostimulation, PLLC

Name of Patient: _____

dTMS Information
My doctor has recommended that I receive treatment with Brainsway Deep repetitive transcranial magnetic stimulation (dTMS).

WHAT IS dTMS?

dTMS is a non-invasive FDA-cleared medical procedure for the treatment of Major Depressive Disorder in adults. dTMS is a brain stimulation technique that relies on the generation of brief magnetic fields using an insulated coil that is placed over the scalp. These magnetic fields are the same type and strength as those used in magnetic resonance imaging (MRI) machines. The magnetic pulses generate a weak electrical current in the pre-frontal cortex region of the brain that briefly activates neural circuits at the stimulation site. dTMS 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 anti-depressant medications.

The potential benefit of Brainsway's unique, patented technology is that it may lead to improvements in the symptoms of my psychiatric condition. I understand that not all patients respond equally well to dTMS. Like all forms of medical treatment, some patients recover quickly, others recover briefly and later relapse, while others may fail to have any response to dTMS.

ALTERNATIVES TO dTMS

I understand that there are alternative treatment options for my condition, including medications, psychotherapy, and electroconvulsive therapy (ECT). My doctor has explained to me the risks and benefits of these other options. My doctor has also explained why dTMS has been recommended for my specific case.

PROCEDURE

dTMS involves a series of treatments. For each dTMS session, I will be comfortably seated on a chair, and a cushioned helmet will be placed over my head. Before the

beginning of the dTMS procedure, I will be asked to remove any metal or magnetic-sensitive objects (e.g. jewelry, glasses, etc.). Because dTMS produces a loud clicking sound with each pulse, I will also be required to wear earplugs for my comfort and safety. dTMS is non-invasive and does not require any anesthesia or sedation, so I will be awake and alert during the entire procedure.

The insulated magnetic coil gently placed over the side or on top of my head will be adjusted by a TMS staff technician by delivering a series of pulses until it gives just enough energy so that my hand twitches. The amount of energy required to make my hand twitch is called the "motor threshold." Everyone has a different motor threshold and the treatments are given at an energy level that is just above my individual motor threshold. This threshold could fluctuate depending on a variety of factors. How often my motor thershold will be re-evaluated will be determined by my doctor. During the procedure, I will hear a clicking sound and feel a tapping sensation on my scalp.

Once my motor threshold is determined, the helmet containing magnetic coil will be moved to the front side of my head, over a region of the brain that scientists think may be responsible for causing depression. I will receive a treatment as a series of "pulses" that lasts about two seconds, with a "rest" period of about 20 seconds between each pulse series. Treatment sessions typically last twenty to thirty minutes.

NUMBER OF TREATMENTS

The exact number of treatments I receive cannot be predicted ahead of time. The number of treatments I receive will depend on my psychiatric condition, my response to treatment, the medical judgment of my psychiatrist, and insurance authorization approval. dTMS treatments are usually administered five times per week and I will likely receive these treatments daily for four to six weeks, and then possibly on a less frequent basis for several weeks thereafter. I will continue to be evaluated at regular intervals by my doctor during this treatment course. Typically patients who respond to dTMS experience results by the fourth to sixth week of treatment. However, some patients may experience results in less time while others may take longer. I may choose to end the treatments at any time.

SAFETY & RISK INFORMATION

The safety of the Brainsway dTMS system was demonstrated in a clinical study involving 233 patients with moderate to severe Major Depressive Disorder. However, as with any other medical procedures and forms of treatment, Brainsway dTMS involves some risks and side effects.

During the treatment, I may experience tapping, facial twitching, or painful sensations at the treatment site while the magnetic coil is turned on. These types of sensations are reported in about one third of patients. I understand that I should inform staff if this occurs. The treatment staff may then adjust the stimulation settings or make changes to where the coil is placed in order to help make the procedure more comfortable for me. In addition, about half of patients experience headaches. 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 dTMS also reported headaches, indicating that the headaches were not necessarily caused by the dTMS treatment. Application site pain and

discomfort was reported in 25% and 20%, respectively, of those subjects participating in the clinical study. I understand that I should inform the dTMS technicians and my doctor if this occurs. The dTMS 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.

The most serious known risk of dTMS is the production of a seizure. Although there have been a few case reports of seizures with the use of TMS devices, the risk is extremely small. There was one case of seizure reported in Brainsway's FDA clinical study due to high alcohol consumption the night before, and three other cases of seizure were reported in other studies (out of approximately 50,000 treatment sessions) in cases of subjects who were on high doses of antidepressants. None of the subjects who have experienced seizure during dTMS treatment have suffered lasting physical sequelae. I understand that I must discuss with my doctor if I have consumed or intend to consume alcohol/drugs prior to teatment. 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, presence of other neurologic disease(s) that may be associated with an altered seizure threshold, 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.

Other side effects which may occur include possible hearing loss, pain in jaw, muscle twitching, anxiety, insomnia, retinal detachment, hypomania, and mania. I understand that I should inform my doctor if I experience any of these adverse events.

There are no known adverse cognitive (thinking and memory) effects associated with dTMS. There are no known long-term adverse effects reported with the use of dTMS. However, as this is a relatively new treatment, there may be unforseen risks in the long-term that are currently unknown.

METAL IMPLANTS

dTMS should not be used by anyone who has non-removable magnetic-sensitive metal in their head or within twelve inches of the magnetic coil, with the exception of standard amalgam dental fillings. I understand that failure to follow restrictions could result in serious injury or death. Examples of restricted metal substances/objects include:

- Aneurysm clips or coils
- Stents in your neck or brain
- Implanted stimulators
- Cardiac pacemakers or implantable cardioverter defibrillator (ICD)
- Electrodes to monitor your brain activity
- Ear/eye ferromagnetic implants
- Metal ink in facial/head tattoos and permanent makeup
- Shrapnel or bullet fragments

There were no deaths in patients who took part in the clinical trial for Brainsway dTMS.

PATIENT VERIFICATION

I have read (or have had read to me) the information contained in this Medical Procedure Consent Form about Brainsway Deep TMS treatment, the process involved in the treatment and its potential risks. I understand there are other treatment options for my depression available to me and this has also been discussed with me. I have discussed it with my doctor, who has answered all of my questions. I understand that I should feel free to ask questions about dTMS at any time before, during, or after the course of treatment and that I may discontinue treatment at any time.

I give permission to the psychiatric providers at Pacific Center for Neurostimulation and the staff of Pacific Center for Neurostimulation to administer this treatment to me.

I have been given a copy of this consent form to keep.

Consent signed on _____, 20___ at _____ AM/PM

_____ _____

Signature of Patient Printed Name

_____ _____

Signature of Witness Printed Name

10740 Meridian Avenue N, Suite 205, Seattle, Washington 98133
phone 206.535.6292 | fax 206.356.1151
www.PacificCNS.com