

## Patient Consent for a Medical Procedure

### TMS Therapy

This is a patient consent for a medical procedure called TMS Therapy. This consent form outlines the treatment that your doctor has prescribed for you, the risks of this treatment, the potential benefits of this treatment to you, and any alternative treatments that are available for you if you decide not to be treated with TMS Therapy.

The information contained in this consent form is also described in the Depression Patient's Manual for Transcranial Magnetic Stimulation with the TMS Therapy<sup>®</sup> System which is available from your doctor. Not all information in the Manual is stated here, so you should read the Patient Manual and discuss any questions that you have with your doctor. Once you have reviewed the manual and this consent form, be sure to ask your doctor any questions that you may have about TMS Therapy.

Dr. \_\_\_\_\_ has explained the following information to me:

- a. TMS stands for "Transcranial Magnetic Stimulation". TMS Therapy is a medical procedure. A TMS treatment session is conducted using a device called the TMS Therapy 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. TMS Therapy is a safe and effective treatment for patients with depression who have not benefitted from antidepressant medications.
- c. Specifically, TMS Therapy has been shown to relieve depression symptoms in adult patients who have been treated with one antidepressant medication given at a high enough dose and for a long enough period of time but did not get better.
- d. During a TMS treatment session, the doctor or a member of their staff will place the magnetic coil gently against my scalp on the left front region of my head. The magnetic fields that are produced by the magnetic coil are pointed at a region of the brain that scientists think may be responsible for causing depression.
- e. To administer the treatment, the doctor or a member of their staff will first position my head in the head support system. Next, the magnetic coil will be placed on the left side of my head, and I will hear a clicking sound and feel a tapping sensation on my scalp. The doctor will then adjust the TMS Therapy system so that the device will give just enough energy to send electromagnetic pulses into the brain so that my right-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. How often my motor threshold will be re-evaluated will be determined by my doctor.

- f. Once motor threshold is determined, the magnetic coil will be moved, and I will receive the treatment as a series of “pulses” that last about 4 seconds, with a “rest” period of about 26 seconds between each series. Treatment is to the left front side of my head and will take about 40 minutes. I understand that this treatment does not involve any anesthesia or sedation and that I will remain awake and alert during the treatment. I will likely receive these treatments 5 times a week for 4 to 6 weeks (36 treatments). I will be evaluated by the doctor \_\_\_\_\_ times during this treatment course. The treatment is designed to relieve my current symptoms of depression.
- g. During the treatment, I may experience tapping or painful sensations at the treatment site while the magnetic coil is turned on. These types of sensations were reported by about one third of the patients who participated in the research studies. I understand that I should inform the doctor or his/her staff if this occurs. The doctor may then adjust the dose or make changes to the where the coil is placed in order to help make the procedure more comfortable for me. I also understand that headaches were reported in half of the patients who participated in the clinical trial for the device. I understand that both discomfort and headaches got better over time in the research studies and that I may take common over-the-counter pain medications such as acetaminophen if a headache occurs.
- h. The following risks are also involved with this treatment:

The TMS Therapy System should not be used by anyone who has magnetic-sensitive metal in their head or within 12 inches of the magnetic 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 includes:

- Aneurysm clips or coils
- Stents
- Implanted Stimulators
- 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. The TMS System should be used with caution in patients who have pacemakers or implantable cardioverter defibrillators (ICDs) or are using wearable cardioverter defibrillators (WCD). Failure to follow this restriction could result in serious injury or death.
- j. TMS Therapy is not effective for all patients with depression. Any signs or symptoms of worsening depression should be reported immediately to your doctor. You may want to ask a family member or caregiver to monitor your symptoms to help you spot any signs of worsening depression.
- k. Seizures (sometimes called convulsions or fits) have been reported with the use of TMS devices. However, no seizures were observed with use of the TMS Therapy system in over 10,000 patient treatment sessions in trials conducted prior to FDA clearance of the TMS System. Since the introduction of the TMS System into clinical practice, seizures have been rarely reported. The estimated risk of seizure under ordinary clinical use is approximately 1 in 30,000 treatments or 1 in 1000 patients.
- l. Because the TMS Therapy system produces a loud click with each magnetic pulse I understand that I must wear earplugs or similar hearing protection devices with a rating of 30dB or higher of noise reduction during treatment.
- m. I understand that most patients who benefit from TMS Therapy experience results by the fourth week of treatment. Some patients may experience results in less time while others may take longer.
- n. I understand that I may discontinue treatment at any time.

I have read the information contained in this Medical Procedure Consent Form about TMS Therapy and its potential risks. I have discussed it with Dr \_\_\_\_\_ who has 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 therefore permit Dr. \_\_\_\_\_ and his/her staff to administer this treatment to me.

---

PATIENT

WITNESS

DATE