HPR
TREATMENT CENTERS

Patient Consent for a Medical Procedure

NeuroStar TMS Therapy

This is a patient consent for a medical procedure called NeuroStar 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 NeuroStar TMS Therapy.

The information contained in this consent form is also described in the "NeuroStar TMS Therapy Patient Guide for Treating Depression" which is available from your doctor. Not all information in the Patient Guide is stated here, so you should read the guide and discuss any questions that you have with your doctor. Once you have reviewed the guide and this consent form, be sure to ask your doctor any questions that you may have about NeuroStar TMS Therapy and its use in treating depression.

Dr. _____ has explained the following information to me:

a. TMS stands for "Transcranial Magnetic Stimulation". NeuroStar TMS Therapy is a medical procedure. A TMS treatment session is conducted using a device called the NeuroStar 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. NeuroStar TMS Therapy is a safe and effective treatment for patients with depression who have not benefitted from antidepressant medications.

c. Specifically, NeuroStar TMS Therapy has been shown to relieve depression symptoms in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

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.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 NeuroStar 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.

e. 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 (20 to 30 treatments). I will be evaluated by the doctor _____ times during this treatment course. The treatment is designed to relieve my current symptoms of depression

f. 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 NeuroStar 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.

g. The NeuroStar TMS Therapy System should not be used by anyone who has:

    1) Magnetic-sensitive metal in their head or within 12 inches (30 cm) of the NeuroStar magnetic coil that cannot be removed. Failure to follow this restriction could result in serious injury or death. These include but are not limited to:

        - Cochlear implants
        - Aneurysm clips or coils
        - Stents
        - 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.

2) Implanted stimulators in or near the head. These may including:

- Deep brain stimulators
- Cochlear implants,
- Vagus nerve stimulators.

The NeuroStar 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.

h. NeuroStar 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.

i. Seizures (sometimes called convulsions or fits) have been reported with the use of TMS devices. However, no seizures were observed with use of the NeuroStar TMS Therapy System in clinical trials involving about 500 patients and over 15,000 treatments. Since the introduction of the NeuroStar 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.

j. Because the NeuroStar 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.

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

l. I understand that symptom relief that I may receive from NeuroStar TMS Therapy may be lost over time and I will need to take antidepressant medication to help retain symptom relief. In clinical trials, 85% of patients retained benefit with antidepressant medication over 12 months. About one-third of these patients required periodic re-treatment with NeuroStar TMS Therapy.

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

I have read the information contained in this Medical Procedure Consent Form about NeuroStar 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