Patient Consent to
TMS Treatment

My doctor has recommended a medical procedure called repetitive Transcranial Magnetic Stimulation or "TMS" Treatment for me. This consent form outlines the nature of TMS treatment, the risks of this treatment, the potential benefits of this treatment, and any alternative treatments that are available if I decide not to receive TMS Treatment.

TMS Center of Colorado, LLC has explained the following information to me:

What is TMS?

a. TMS stands for "Transcranial Magnetic Stimulation." TMS Treatment is a medical procedure. A TMS treatment session is conducted using a device called the TMS Treatment 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. The magnetic pulses generate a weak electrical current in the brain that briefly activates neural circuits at the site of stimulation.

b. TMS Treatment has been shown to be a safe and effective treatment for patients with certain mental disorders who have not benefitted from medication or other traditional treatments. The U.S. Food and Drug Administration (the "FDA") has permitted use of TMS as a treatment for major depressive disorder and obsessive compulsive disorder. While the FDA may not have specifically approved the use of the TMS system for other disorders, healthcare providers are permitted to use the treatment for an "unapproved" or "off-label" use when the provider considers such treatment is medically appropriate for the patient.

   I understand that my treatment is for an ____approved ____off-label use (initial one) for the treatment of _____.

Procedure

a. For each TMS treatment session, I will be brought into a specially equipped room and will be asked to remove any metal or magnetic-sensitive objects such as jewelry, credit cards, etc. Because the TMS Treatment 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 for my comfort and safety. TMS does not require anesthesia or sedation, so I will be awake and alert during the entire procedure.

b. The doctor or a TMS Center staff member will place the magnetic coil gently over the side or top of my head, depending on the requirements for my treatment.

   During the treatment, I will hear a clicking sound and feel a tapping sensation on my scalp. The doctor will adjust the TMS Treatment system so that the device will give just enough energy to send electromagnetic pulses into the brain until there is a slight twitching in my limbs – either my feet or right hand

c. The amount of energy required to make me twitch is called the "motor threshold". I understand that everyone has a different motor threshold and the treatments are given at an energy level that is equal to or just above my individual motor threshold. How often my motor threshold will be reevaluated will be determined by my doctor.

   Once my motor threshold is determined, the magnetic coil will be moved, and I will receive the treatment as a series of "pulses," usually with a brief "rest" period. Most protocols have a rest period of 10 - 20 seconds between each series.

d. Treatment generally takes about 20-45 minutes. I can expect to receive these treatments 5 times a week for 6 weeks, a total of 30 treatments unless my doctor prescribes otherwise. I understand that additional treatments may be required in order for me to receive the greatest benefit from TMS treatment.

Potential Benefits of TMS Treatment

a. My doctor has recommended TMS treatment because it may lead to improvements in the symptoms of my mental disorder I understand that not all patients respond equally well to TMS, and that some patients recover quickly, others recover briefly and later relapse, and others fail to experience any improvement from TMS therapy.

b. I understand that most patients who benefit from TMS Treatment experience results by the fourth week of treatment. Some patients may experience results in less time while others may take longer or may not benefit at all.

c. **I understand that I may discontinue treatment at any time, although I will remain responsible for payment for treatments I have received**.

Risks of TMS Treatment

As with any medical treatment, there are certain risks involved in receiving TMS treatment.

a. During the treatment, I may experience tapping or painful sensations at the treatment site while the magnetic coil is turned on. It is also common to experience facial twitching as

well as slight arm/hand twitching. I understand that I should inform the doctor or the TMS staff if this occurs. The doctor or staff may then adjust the dose or make changes to where the coil is placed in order to help make the procedure more comfortable for me.

b. I understand that it is common to experience headaches related to my treatment. Headaches typically get better over time and generally were relieved with over-the-counter pain medications such as acetaminophen. It is also very common to feel fatigued after treatment.

c. The TMS Treatment System should not be used by anyone who has magnetic-sensitive metal in his or her head or that is within 12 inches of the magnetic coil and cannot be removed. **Failure to follow this restriction could result in serious injury or death**. Objects that may have this kind of metal include:

- Aneurysm clips or coils
- Stents
- Implanted Stimulators
- Cardiac pacemakers or implantable cardioverter defibrilator
- 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 metallic or magnetic-sensitive ink.

d. TMS Treatment is not effective for all patients who suffer from _____. If I or those around me notice any negative change in or worsening of my symptoms, or I experience mania or other new symptoms I will report them immediately to my doctor and/or the TMS Center staff. I have been advised to ask a family member, friend or caregiver to monitor my symptoms to help me spot any signs that they have worsened.

d. Occasionally, TMS treatment causes seizures (sometimes called convulsions or fits) I will let my doctor know before my treatment if I have a history of a seizure disorder or if I experience a seizure at any time after my treatment.

e. I understand that if the ear protection devices I must wear to protect my hearing should become loose or fall out during my treatment I will notify the person administering my treatment immediately.

f. I understand that the risks of exposure to TMS during pregnancy are unknown. I will inform my doctor before my treatment begins if there is any chance that I may be pregnant.

g. I understand that there may be other unknown risks to the use of TMS treatment and that the long-term effects are not yet known.

h. _____ (insert any other risks related to the patient's specific illness)

Other Treatment Options

My physician has explained that there are other treatment options for my illness, including:

_____

I have read the information contained in this Patient Consent Form about TMS Treatment and its potential risks regarding treatment for my diagnosis of _____. I have discussed TMS treatment with Dr. _____ and the TMS Center of Colorado, LLC staff who have answered all of my questions to my satisfaction. I understand there are other treatment options for my condition available to me and this has also been discussed with me. I further understand that no guarantee of any results of TMS treatment has been made. I, therefore, permit TMS Center of Colorado, LLC and its staff to administer a course of TMS treatment to me. If my treatment involves an "off-label" use of TMS, I have been informed of that as well as the particular risks and benefits of such use ____(initial if applicable). My decision to receive TMS treatment is being made on a voluntary basis. I understand I can withdraw my consent at any time and have the treatments stopped.

PATIENT NAME (PRINT): _____

_____ _____ _____

PATIENT SIGNATURE WITNESS DATE

_____

Signature of health care provider securing consent