DEEP TRANSCRANIAL MAGNETIC STIMULATION (TMS)

Attending Physician: Deborah Kim, M.D.

Potential Benefit to You:

It has been recommended based, on your clinical assessment with us, that you receive Brainsway Deep Transcranial Magnetic Stimulation (TMS), as it appears that your condition may potentially benefit from this procedure. This is based on my clinical experience with TMS and on evidence from research that your condition may improve in response to a course of TMS. You have been given the chance to ask any questions you may have prior to the start of treatment.

My doctor has explained the following information to me:

I. About Brainsway Deep TMS Technology

1. Deep TMS stands for “Deep Transcranial Magnetic Stimulation.” Brainsway Deep TMS is a

non - invasive medical procedure. A treatment session is conducted using a device called the

Brainsway Deep TMS System, which delivers pulsed magnetic fields similar in type and strength

as those used in magnetic resonance imaging (MRI) machines.

2. The magnetic fields created by Brainsway’s unique, patented technology allow for the

targeting and stimulation of the neurons contained in the pre-frontal cortex region of the brain.

3. Brainsway Deep TMS is non-invasive, which means that no surgery or incisions into the body

are needed.

4. The FDA cleared the Brainsway Deep TMS 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.

5. The FDA cleared the Brainsway Deep TMS treatment for patients suffering from Obsessive Compulsive Disorder.

Description of Alternative Treatments That Might Prove Equally Advantageous:

You have been told that there are other approved, conventional treatments for your condition, including medications, psychotherapy, electroconvulsive therapy (ECT), and vagus nerve stimulation (VNS). These alternative treatments have their own benefits and risks. You understand that the question of whether TMS is most appropriate for you depends on your prior experiences with these treatments, the nature of your psychiatric condition, and other considerations. The alternative to receiving TMS would be to receive conventional treatment (medications, psychotherapy, and/or ECT or VNS).

Description of Procedures:

TMS is given using a magnetic stimulator. A magnetic stimulator is a device that generates a magnetic field. The magnetic field is produced by passing an electric current through an

insulated coil of wire that is held on the scalp. The coil is insulated so that the electricity stays completely inside the coil. Electricity does not directly pass through the coil onto the scalp. The magnetic field generated by the coil passes through the skull into the brain. By rapidly turning the magnetic field on and off, a small amount of electricity is briefly produced in the brain.

TMS involves a series of treatment sessions, typically given 5 times a week. Each session lasts for about 20-30 minutes. The exact number of sessions will be determined by your doctor based upon your response. The TMS sessions will be performed in a specially equipped room. Before beginning the TMS procedures, you will be asked to remove any metal or magnetized objects (such as keys, jewelry, and credit cards). TMS produces a loud clicking sound, so you will be required to wear ear plugs during the entire TMS session. Trained staff will always be with you. If undesirable side effects develop, you may stop the procedure at any time.

Any treatment procedures that fall outside of the treatment studies submitted to the FDA as part of the FDA approval process will be offered at Dr. Kim’s discretion. You will be kept fully informed of whether the offered procedure is considered typical or experimental. You can accept or refuse any of Dr. Kim’s recommendations and this will not affect your care with her. You understand all risks and benefits will be fully described, if different from what is in this consent form.

To determine the intensity of the magnetic stimulation needed in your particular case, you will undergo a test called a motor threshold. The motor thresholds examine the excitability of areas of the brain by testing the response of your hands or feet to TMS at a slow rate. “Excitability” refers to how strong the TMS has to be to make your fingers or toes twitch. These procedures require that you sit quietly in a chair for about 10 minutes. Dr. Kim will hold the magnetic stimulator over your head that emits a magnetic pulse. A series of pulses will be emitted until this causes your finger muscle to twitch (feet for OCD treatments). During the procedure the only effect you are likely to notice is a clicking noise when the magnetic pulses are produced. You will wear earplugs during the procedure to protect your hearing. Everyone has a different motor threshold and the treatments are given at an energy level that is just above your individual motor threshold. This threshold could fluctuate depending on a variety of factors. Dr. Kim will determine how often your motor threshold will be re-evaluated.

Risks:

TMS may have unknown side effects. You must inform the staff and your TMS administrator of any new medications or changes to existing medication that you are taking. Failure to do so may increase your risk of side effects from TMS, including the likelihood of increased risk of developing seizures. The most serious know risk of TMS is the production of a convulsion (seizure). TMS can produce a convulsion when series of pulses are given at high power and when the series are given extremely close together. TMS has produced convulsions in some patients with epilepsy. The literature contains reports of hundreds of normal volunteers and patients with depression receiving trains of TMS. Six normal volunteers receiving TMS have had a convulsion. The TMS team follows the published safety guidelines for the use of TMS that are designed to avoid risk factors for convulsions with TMS.

The strength of the magnetic field used for trains of stimulation will be adjusted to your individual response to single magnetic pulses, as tested with the motor threshold procedure described above. Persons with epilepsy, a history of convulsions in childhood (“febrile convulsions”), and a family history of treatment-resistant epilepsy may be at higher risk of convulsion with TMS. Also, if you have a history of head trauma, implanted metal objects, or neurological disorder, you may be at higher risk. You will continuously monitored during the stimulation sessions by trained staff. If warning signs of a convulsion appear, the stimulation will be stopped immediately. In spite of these precautions, there is a chance that you will experience a convulsion or other medical complication. If you have a convulsion, you may require hospital admission and follow-up neurological evaluation. Having had a convulsion may adversely affect your medical insurability, your future employment, and your ability to drive. It is not known whether having had one convulsion will make a person more prone to have future convulsions.

The most commonly reported side effect of TMS is headache. 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. Neck pain may also occur. If a headache or neck pain occurs, they are usually easily managed with standard analgesics (pain killers, such as aspirin). You may experience some discomfort on you head where the coil is held. This is due to contraction of muscles and stimulation of nerves on the scalp. The clicking noise made by the stimulator may temporarily affect hearing. Ear plugs reduce this risk; therefore, you will be asked to wear earplugs during TMS.

Application site pain and discomfort was reported in 25% and 20%, respectively, of those participating of the subjects participating in the depression clinical study. You understand that you should inform the treatment administrator if you 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. Other side effects, which may occur, include pain in jaw, muscle twitching, back pain, anxiety and insomnia. You understand that you should inform the doctor if you experience any of these adverse events.

Because Brainsway Deep TMS may take a few weeks before symptom improvement occurs, in the meantime your depression may worsen, and increased mood instability and thoughts of suicide could occur. You understand that if you experience these symptoms, your doctor should be notified immediately.

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. You understand that failure to follow this restriction could result in serious injury or death.

Deep TMS should be used with caution and only upon close consultation

with a doctor by patients who have implanted electronic devices (such as pacemakers,

implantable cardioverter defibrillators [ICDs] or wearable cardioverter defibrillators [WCDs]) in

their body. I understand that failure to follow this restriction could result in serious injury or

death.

The risks of exposure to magnetic fields during pregnancy have been studied but only in small studies. You may be asked to take a pregnancy blood test before exposure to magnetic stimulation if you are woman of child-bearing capacity. If you are in this category, you agree to use an effective form of contraception until after the course of TMS sessions are completed. If you are pregnant, Dr. Kim will discuss and document the discussion of any additional risks associated with deep TMS during pregnancy.

Costs and Compensation:

The Deep TMS Treatment Program at this practice is not covered by insurance. You will be responsible for all fees in relation to this service. The practice does not provide compensation or payment for treatment or injuries related to this procedure, nor for wages lost as a result of injury. However, you are aware that participation in this procedure does not waive any of your legal rights to seek such compensation through the courts. You have had the time to answer all questions related to the financial cost to you of TMS. You must pay weekly and TMS may be stopped if you do not pay. You will be provided with receipts and forms that will allow you to seek reimbursement from your insurance company as “out of network treatment benefits”, if offered by your insurance company. Beyond providing these receipts, you understand the TMS doctor and staff will not be interacting or talking to your insurance company.

Rights of Participants:

The nature of this procedure and possible side effects have been clearly explained to you both in writing and verbally. Your participation in this procedure is completely voluntary. You may refuse to participate or withdrawal at any time, without loss of benefits to which you are otherwise entitled. You understand your right to privacy and the confidentiality of your participation in this procedure, should you choose to participate, will be safeguarded. Your records, like other medical and clinical records, will be kept confidential to the extent permitted by law. Any information obtained during this procedure and identified with you will remain confidential to the extent permitted by law, and will otherwise only be available to staff, institutional personnel, or to federal and Pennsylvania regulatory personnel. You will be notified of significant new findings that may relate to your willingness to continue to receive this procedure.

Questions:

The conduct of TMS at this facility is under the direction of Dr. John O’Reardon. All questions you have about this procedure have been answered by Dr. O’Reardon, or his staff, to the best of their ability. If you have further questions about the procedures or about your response to the procedures, you may contact Dr. O’Reardon at 856-375-2406. You will be given the opportunity to discuss in confidence any questions you may have.

Verification and Statement of Consent:

The nature of this procedure and possible side effects have been clearly explained to you both in writing and verbally. You understand that your consent to this procedure is voluntary and that you can withdrawal consent at any time without prejudice. You have read the above and give your consent to receive the TMS procedure. Signing this form does not waive any of your legal rights. You have been given a copy of this consent form for you to keep.

Signature of participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_

I have discussed the proposed procedure with this patient and, in my opinion, this patient understands the benefits, risks and alternatives (including non-participation) and is capable of freely consenting to participate in these procedures.

Clinician obtaining consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of clinician \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_