



## DEEP REPETITIVE TMS/dTMS TREATMENT – INFORMED CONSENT FORM

Name of Patient: \_\_\_\_\_

My doctor has recommended I receive treatment with Deep Repetitive TMS/dTMS (Deep Transcranial Magnetic Stimulation). The nature of this treatment, including the benefits and risks I may experience, has been fully described to me and I give my consent to be treated with Deep Repetitive TMS/dTMS.

I will receive Deep Repetitive TMS/dTMS therapy to treat my psychiatric condition. I understand there may be other alternative treatments for my condition. Information regarding Deep Repetitive TMS/dTMS is also described in the “Patient Manual” provided by my doctor, which I have had an opportunity to review.

My doctor has explained the following information to me:

### I. about Deep Repetitive TMS/dTMS Technology

1. Deep Repetitive TMS/dTMS stands for “Deep Transcranial Magnetic Stimulation.” Deep Repetitive TMS/dTMS is a non-invasive medical procedure. A treatment session is conducted using a device called the Deep Repetitive TMS/dTMS 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 unique, patented technology allow for the targeting and stimulation of the neurons contained in the pre-frontal cortex region of the brain.
3. Deep Repetitive TMS/dTMS is non-invasive, which means no surgery or incisions into the body are needed. Deep Repetitive TMS/dTMS does not require the use of pharmaceutical products; therefore, patients may be able to avoid many of the physical and biological side effects often associated with drug consumption. Deep Repetitive TMS/dTMS also avoids the need for anesthesia, thereby eliminating certain side effects associated with Electro-Convulsive Therapy (ECT). Nevertheless, the Deep Repetitive TMS/dTMS treatment is associated with certain adverse events which are detailed in the Patient Manual.
4. The FDA cleared the Deep Repetitive TMS/dTMS 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 completion of a multicenter study in the US and abroad which was conducted to investigate the safety and efficacy of the Deep Repetitive TMS/dTMS treatment.

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## II. The Treatment Process

1. During a treatment session, I will be comfortably seated on a chair, and a coil will be gently placed near my head. The coil generates brief magnetic fields, similar to those used in magnetic resonance imaging (MRI) systems. These magnetic fields briefly stimulate a targeted brain area and improve depressive symptoms.
2. During the course of the treatment, I will hear a clicking sound and feel a tapping sensation on my scalp. The operator will ask me if I want to use standard earplugs during the treatment. The operator will then adjust the Deep Repetitive TMS/dTMS 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. This threshold could fluctuate depending on a variety of factors. How often my motor threshold will be re-evaluated will be determined by my doctor.
3. Once motor threshold is determined, the coil will be moved, and I will receive the treatment as a series of “pulses” that last about 2 seconds, with a “rest” period of about 20 seconds between each series. Although each patient is different, each treatment generally takes about 20 to 23 minutes. This treatment does not involve any anesthesia or sedation and I will remain awake and alert during the entire course of the treatment. I will likely receive these treatments daily for four weeks, and sometimes it involves additional treatments once every 2 weeks for a 12-week period. My treatment will be closely medically supervised.
4. I understand most patients who benefit from Deep Repetitive TMS/dTMS experience results by the third or fourth week of treatment. Some patients may experience results in less time while others may take longer.
5. My doctor has informed me about any applicable fees and/or insurance coverage involved in receiving Deep Repetitive TMS/dTMS treatment.
6. I understand information obtained within the context of treatment is confidential and can ordinarily be released only with my written permission. I further understand there are some special circumstances that can limit confidentiality including: a) a statement of harm to myself or others; and/or b) issuance of a subpoena from a court of law. I further understand it is foreseeable although not likely certain basic patient information might in the future be requested by from my doctor, and that any such requests will, to the extent possible, take into consideration my rights with respect to confidentiality.

## III. Safety & Risk Information

\_\_\_\_\_Initial 1. The safety of the Deep Repetitive TMS/dTMS System was demonstrated in a clinical study involving 233 patients with moderate to severe Major Depressive Disorder. However, like other medical procedures and forms of treatment, Deep Repetitive TMS/dTMS involves some risks and adverse events.

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\_\_\_\_\_Initial 2. Seizures (sometimes called convulsions or fits) have been reported with the use of TMS devices. There was one case of seizure reported in 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 the Deep Repetitive TMS/dTMS treatment have suffered lasting physical sequelae. I understand I must discuss with my doctor if I have consumed or intend to consume alcohol/drugs prior to treatment. I understand 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 or presence of other neurologic disease that may be associated with an altered seizure threshold, or concurrent medication or other drugs that are known to lower the seizure threshold, secondary conditions which may significantly alter electrolyte balance or lower seizure threshold, or where a quantifiable motor threshold cannot be accurately determined.

\_\_\_\_\_Initial 3. 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 Repetitive TMS/dTMS also reported headaches, indicating the headaches reported by Deep Repetitive TMS/dTMS patients were not necessarily caused by the Deep Repetitive TMS/dTMS treatment. Headaches usually get better or go away completely with successive treatments. Additionally, headaches may be relieved by over-the-counter medicine such as acetaminophen or Ibuprofen. I understand I should inform my doctor if this occurs.

\_\_\_\_\_Initial 4. Application site pain and discomfort was reported in 25% and 20%, respectively, of the subjects participating in the clinical study. I understand I should inform the treatment administrator if I feel pain or discomfort during the treatment. The Deep Repetitive TMS/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.

\_\_\_\_\_Initial 5. Other side effects which may occur include pain in jaw, muscle twitching, back pain, anxiety and insomnia. I understand I should inform my doctor if I experience any of these adverse events.

\_\_\_\_\_Initial 6. If I am currently on antidepressant medications, my doctor may taper down my dosage prior to and during the course of Deep Repetitive TMS/dTMS treatment. Because Deep Repetitive TMS/dTMS may take a few weeks before symptom improvement occurs, in the meantime my depression may worsen and increased mood instability and thoughts of suicide could occur. I understand that if I experience these symptoms, my doctor should be notified immediately.

\_\_\_\_\_Initial 7. I understand Deep Repetitive TMS/dTMS 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. I understand failure to follow this restriction could result in serious injury or death.

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\_\_\_\_\_Initial 8. I understand Deep Repetitive TMS/dTMS 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 failure to follow this restriction could result in serious injury or death.

\_\_\_\_\_Initial 9. During treatment with the Deep Repetitive TMS/dTMS System a loud clicking sound is emitted. Therefore, patients must use earplugs with a rating of at least 30 dB of noise reduction. There have been no reports of hearing loss with the Deep Repetitive TMS/dTMS Treatment in the clinical study when earplugs were used.

\_\_\_\_\_Initial 10. There were no deaths in patients who took part in the clinical trial for Deep Repetitive TMS/dTMS, systematic side effects such as weight gain, dry mouth and sexual problems were not observed, and no changes to memory function were shown.

IV. Alternate Treatment Options

\_\_\_\_\_Initial 1. While my doctor has recommended Deep Repetitive TMS/dTMS for me, I understand a variety of other treatment options for depression exist which may be suitable for me. Which treatment option is right for me depends on a variety of factors including but not limited to previous experience, severity of my disorder, potential side effects and other factors and risks.

Other treatment options might include:

- Psychotherapy
- Medication
- Electro-Convulsive Therapy (ECT)
- Surface/Ordinary Transcranial Magnetic Stimulation (TMS)

\_\_\_\_\_Initial 2. I understand Deep Repetitive TMS/dTMS is not effective for all patients with depression. I will report any signs or symptoms of worsening depression immediately to my doctor. I understand that it is advisable to have a family member or caregiver monitor any symptoms and to assist in spotting any signs of worsening depression.

Additional Information:

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PATIENT VERIFICATION

I have read the information contained in this Medical Procedure Consent Form about Deep Repetitive TMS/dTMS 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 I should feel free to ask questions about Deep Repetitive TMS/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 doctor and his or her staff 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/or Guardian

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Printed Name