Patient Consent for
Transcranial Magnetic Stimulation (TMS Therapy)

This is a patient consent for a medical procedure called TMS Therapy®. This consent form outlines the treatment that the 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 discussed with you during you're initial TMS therapy consultation visit. Not all information in the TMS Consultation may be stated here, so you should be sure to discuss any questions that you have with the doctor or Certified TMS Technician. Once you have reviewed the guide and this consent form, be sure to ask any questions you may have about TMS Therapy and its use in treating depression.

The following information has been explained 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: CloudTMS, 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 an FDA-approved treatment for patients with depression who have not benefitted from antidepressant medications and is considered safe and effective.

c. Specifically, 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. The magnetic fields that are produced by the magnetic coil are pointed at a region of the brain that scientists have proven may be responsible for causing depression. To administer the treatment, the doctor or a member of their staff will first position my head appropriately. Once treatment begins,

I will hear a clicking sound and feel a tapping sensation on my scalp. The device will be adjusted by the doctor and will give just enough energy to send electromagnetic pulses into my 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 and depends on my initial response to the treatment.

e. Once my motor threshold is determined, the magnetic coil will be moved, and I will receive the treatment as a series of “pulses”. I understand that this treatment does not involve any anesthesia or sedation and that I will remain awake and alert during the treatment. For optimal results, I will receive either the standard protocol of 5 treatments per week for 4 to 6 weeks (up to 36 treatments) for treatment sessions lasting approximately 20 minutes or my doctor may administer a shortened treatment protocol called “theta burst” where I may receive multiple brief treatments several times a day for 5-7 days. The doctor may likely evaluate my response to the treatment one to two times during the course of treatment.

f. During the treatment, I may experience a tapping sensation at the treatment site while the magnetic coil is turned on. I understand this '*tapping*' may be uncomfortable for me, and for some people, may be perceived as painful. I understand that I should inform the doctor or his/her staff if unable to tolerate the '*tapping*'. The doctor or technician may then adjust the dose or make changes to where the coil is placed to help make the procedure more comfortable for me. I also understand that I may experience a headache after treatment. I understand that both discomfort and headaches are a potential side effect but often lessen over time. I may take an over-the-counter medication if a headache occurs.

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

1) Magnetic-sensitive metal in their head or within 12 inches (30 cm) of the 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:
2) Cochlear implants
3) Aneurysm clips or coils
4) Stents
5) Electrodes to monitor your brain activity
6) Ferromagnetic implants in your ears or eyes
7) Bullet fragments
8) Other metal devices or objects implanted in the head

9) Facial tattoos with metal ink or permanent makeup

10) Implanted stimulators in or near the head. These may include:

    a. Deep brain stimulators

    b. Cochlear implants,

    c. Vagus nerve stimulators

TMS System should be used with caution in patients who have pacemakers or implantable cardioverter defibrillators (or are using wearable cardioverter defibrillators (WCD). Failure to follow this restriction could result in serious injury or death.

TMS Therapy is not effective for all patients with depression or other condition. Any signs or symptoms of worsening depression or other related symptoms 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 symptoms. It is important to note that during the first 2-weeks (especially over the first couple weekends - Saturday/Sunday) you may feel '*more down than usual'* as the treatment begins to work.

h. While very rare, seizures have been reported with the use of TMS devices. The estimated risk of seizure under ordinary clinical use is approximately 1 in 30,000 treatments or 1 in 1000 patients.

i. Because the TMS Therapy system produces a loud click with each magnetic pulse, I understand that I should wear earplugs with a rating of 30dB or higher or sign a waiver to decline hearing protection devices during treatment.

j. 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, including noted improvement up to 2-weeks post treatment.

k. I understand that symptom relief from TMS Therapy may be lost over time and I may need to take antidepressant medication to help retain symptom relief. I understand that approximately one-third of patients require re-treatment TMS Therapy in approximately six to eighteen months, as I acknowledge that every patient responds differently. New research indicates that periodic maintenance treatments or annual treatment optimizes symptom relief, and thus offers longer remission periods from depression.

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

COVID-19 Acknowledgment:

I understand that during my treatment certain precautions will be taken to maintain a safe and clean environment for others and myself. I can expect that staff will wash their hands in between patients and properly clean equipment in between patient treatments. I understand

and agree to report any symptoms related to COVID19, such as a fever, cough, or sore throat. I understand that my treatment may be interrupted if I experience symptoms of COVID19 or if I've come into contact with someone who has tested positive for COVID19, and that I may restart or resume treatment when I no longer exhibit symptoms of COVID19 for a minimum of 14-days or upon proof of testing negative for COVID19. I understand that while CNY TMS Psychiatry is taking every precaution to prevent the spread of COVID19, there is no guarantee that I will not contract COVID19 during the course of my treatment. Should another patient or staff member of CNY TMS Psychiatry contract COVID19, I understand that I will be informed of this occurrence. Should I develop COVID19 during the course of my treatment, I understand that CNY TMS Psychiatry has an obligation to notify their staff and other patients and that none of my personal health information will be shared as part of this notification.

I acknowledge and understand the above COVID19 policies and procedures and understand that if I have any questions related to this policy or regarding possible COVID19 symptoms, I may call the office for clarification.

I have read the information contained in this Medical Procedure Consent Form about TMS Therapy and its potential side effects and/or risks. I have all of my questions answered. I understand there are other treatment options for my condition available to me, such as medications and psychotherapy and this has also been discussed with me.

I therefore permit Dr. _____ and his/her Certified TMS Therapy staff to administer TMS therapy treatment to me.

_____ _____

PATIENT NAME (PRINTED) DATE

_____

PATIENT SIGNATURE

_____ _____

WITNESS (TMS EMPLOYEE) DATE