



This document is effective from: _____ to: _____

Individualized Transcranial Magnetic Stimulation Consent

Individualized Transcranial Magnetic Stimulation (TMS) is a non-invasive therapy using electromagnetic stimulation of the brain. The magnetic field produced by the procedure is similar to that of magnetic resonance imaging (MRI). Individualized TMS has shown great promise in the treatment of certain conditions or disorders that are not responsive to conventional methods of treatment such as medications, psychotherapy, or other interventional procedures.

TMS is administered by placing a special coil (magnetic) over the head while the patient remains seated in a comfortable chair. A powerful, painless, magnetic field delivers a pulse or stimulus that travels approximately _____centimeters through the skull based on a specific treatment protocol ordered by a Certified TMS Physician. Each session takes approximately _____seconds or _____minutes. Patients are thoroughly screened and evaluated before the treatment and are monitored during the treatment session by a trained and certified neuromodulation technician or other certified clinician or practitioner to monitor the patient’s response to the treatment and coil contact. There is no guarantee that patients will respond positively to TMS therapy, as each patient responds differently to treatment. However, approximately 50% of patients receiving Individualized TMS respond favorably. As with all therapies or medications, there is a chance for side effects, such as headache, discomfort at the site of treatment, or seizure. Transcranial magnetic stimulation is FDA-approved for specific conditions, such as major depressive disorder in adult patients, and other conditions depending on the TMS system being used for treatment. The results of research and clinical trials have shown improvement and positive results in patients suffering from various neuropsychiatric disorders including anxiety, attention deficit disorder, autistic spectrum disorder, mild and moderate traumatic brain injury, bipolar disorder, headache, certain types of chronic neuropathic pain, substance abuse, dementia, and other psychiatric and neurological conditions.

ALTERNATIVE TREATMENT: There are no specific alternatives for individualized transcranial magnetic stimulation therapy. There may be alternative treatments and therapies for the patient’s illness. You are encouraged to consider all treatment options for your diagnosis.

You are free to stop therapy at any time. *Initial* _____

SIDE EFFECTS: About ten percent (10%) of patients receiving TMS will experience headaches and/or discomfort at the treatment site that may last several hours following the treatment. Some patients experience exacerbation or recurrence of previous symptoms during the early phase of treatment. Side effects generally subside after the first few treatment sessions. In certain circumstances seizures have been shown to occur, as with psychotropic and other medications. This average risk is below 1 per 30,000. By contrast, the chance of being in a motor vehicle accident is 1 per 10,000.

Initial _____

“Off-label” is a term used when a doctor uses FDA-approved technology in a different manner than the FDA had approved. Any doctor can use any FDA-approved technology if the doctor believes it will help the patient. Individualized Transcranial Magnetic Stimulation is the off-label use of Transcranial Magnetic Stimulation. Off-label use of FDA-approved technology is lawful pursuant to 21 U.S. Code 396 and acknowledged by the FDA. Many physicians use medications and other therapies and treatments, including TMS therapy, for off-label uses when he/she feels the patient may benefit from such treatment.

Initial _____

Consent to treatment: I have been informed of the effects, side effects, benefits and risks of the treatment listed above and give my consent voluntarily to participate in this treatment.

 Medical Director or Physician

 Patient Name

 Signature of Witness

 Signature

 Title of Witness

 Date