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This document is effective from: 01/01/2014 to: 12/31/2015

Individualized Transcranial Magnetic Stimulation Consent

Individualized Transcranial Magnetic Stimulation is a non-invasive therapy using electromagnetic stimulation of the brain. The magnetic field produced by the procedure induces trace amounts of electrical current in the brain. It is used after diagnosis for treatment and has shown great promise in the treatment of many conditions that are not responsive to conventional treatments.

The procedure is administered by placing a special coil over the head while the patient remains seated in a chair. A powerful, painless, magnetic field is pulsed into the brain for a few seconds every minute of the session. Each session takes approximately thirty minutes. Patients are carefully screened before the procedure by EEG and are monitored during and following the procedure to minimize any risk from the procedure.

There is no guarantee that patients will respond positively to this therapy and as with all therapies, there is a chance of injury. However, results of research and clinical trials have shown improvement and positive results in patients suffering from various neuropsychiatric disorders including major depression, cognitive decline from chemotherapy, anxiety, attention deficit disorder, autistic spectrum disorder, mild and moderate traumatic brain injury, concussion, substance abuse, and other psychiatric conditions.

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

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

In certain circumstances seizures have been shown to occur. However, this protocol has been adjusted to minimize potential of a seizure occurring. This risk is below 1 per 100,000. By contrast, the chance of being in a motor vehicle accident is 1 per 10,000.

About ten percent (10%) of patients undergoing this procedure will experience headaches and/or lightheadedness that will last several hours following the procedure. Patients may experience transient excitement, aggression, and/or sleep difficulty. Some patients experience exacerbation or recurrence of previous symptoms during the early phase of treatment. *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 as lawful. *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