Consent Form for Treatment Course of Transcranial Magnetic Stimulation

As a patient receiving a course of treatment with Transcranial Magnetic Stimulation (TMS) I will be undergoing treatment for my depression that has not responded to medication. I agree and expect that providers of the treatment, whether Dr. Turell or one of his associates, has been trained on the performance of TMS mapping and TMS treatment protocols and administration.

In order to rule out risk factors and contraindication for TMS I state that:

1. I do not have a current serious medical condition

2. I do not have a history of a neurological disorder, head trauma, stroke, brain surgery, epilepsy or family history of epilepsy.

3. I do not have any metal implants in my head, any implanted medication pump or a pacemaker in my body.

4. I am not currently pregnant and aware that the risks of exposure to a magnetic field during pregnancy are not fully understood till present.

Procedures

During the course the of treatment, providers will be applying the following TMS techniques:

1. Single pulse stimulation of the motor cortex with the Magstim Horizon device.

2. Repetitive Transcranial Magnetic Stimulation (rTMS) over the prefrontal cortex with the Magstim Horizon device.

General description of TMS

Transcranial Magnetic Stimulation is applied through a Magnetic Stimulator. A Magnetic Stimulator is a set of electrical capacitors which can store and rapidly discharge electricity into a copper coil of electrical wire that is encased in plastic. This plastic case is held resting on the head of the subject. As the electrical current flows between the two coils, a magnetic field is generated that penetrates skin and skull and induces a second electrical flow of current in the brain. This is not painful but may eventually be uncomfortable depending on the stimulation intensity used. Subjects will hear a clicking noise as the current flows through the coil and experience involuntary activation of different muscle groups depending on the positioning of the coil over the motor cortex. Depending on the purpose of the study there will be magnetic stimulation with single pulses, paired pulses or repetitive stimulation at various frequencies between 1-20 Hz(cycles per second).

Single Pulse Stimulation is used for determination of the optimal site of stimulation for certain motor areas. It is always used to initially determine the motor threshold (MT; intensity of the maximal output of the stimulator in percent at which 50% of stimuli evoke a motor response) of each subject to individualize the stimulation parameters according to safety guidelines.

Repetitive Transcranial Magnetic Stimulation (rTMS) is used to enhance or inhibit the activity of certain areas of the brain in order to either influence diseases as for example. The intensity applied will always

be individualized according to participants' motor threshold and not exceed 90% of motor threshold. This is an arbitrary number derived from the safety guidelines summarized by Dr. E. Wassermann. The frequency of stimulation as well as the total number of stimuli and the duration of each train of stimulation will be applied according to these guidelines. A copy of these safety guidelines is attached to this consent form.

Risks and Discomforts

TMS has been used in a growing number of laboratories and clinical settings worldwide since 1985. A series of adverse effects that can be induced by TMS have been identified. The risks of such adverse effects that can be induced by TMS have been identified. The risk of such adverse effects depends greatly on the form of stimulation employed.

During the treatment course of TMS all currently recommended safety precautions will be practiced. I understand that the following side effects are possible:

1. Approximately 10 in every 100 patients undergoing TMS experience headaches, which are believed to be due to excessive muscle tension. Headaches may also be due to the pressure of the tightly fitting swimming cap that I will have to wear to mark out the proper sites for stimulation. In the case of a headache I will be offered acetaminophen (Tylenol) or aspirin which in most cases promptly resolves the discomfort.

2. Approximately 1 in every 100 patients undergoing TMS experiences neck stiffness and neck pain. This is believed to be due to the straight posture of the head and neck during the application of TMS. In the case of such an event I will be offered acetaminophen (Tylenol) or aspirin which in most cases promptly resolves the discomfort.

3. TMS produces a loud clicking noise when the current passes through the coil. This loud click can result in tinnitus and transient decreased hearing if now protection is used. To prevent this adverse effect all participants whether giving TMS or receiving it will be given earplugs to wear. Animal and human studies have demonstrated that earplugs can effectively prevent the risk of hearing disturbances due to TMS.

4. TMS can induce a convulsion even in the absence of brain lesions, epilepsy or other risk factors for seizures. At least 7 cases of convulsions induced by TMS in subjects without risk factors for epilepsy have been reported despite the fact that many thousands of subjects have been studied in the past decade worldwide. The overall risk for seizures during TMS is thought to be in the order of 1 in 1000 studies. The forms of magnetic stimulation during the treatment course of TMS are within the limits recommended by the guidelines.

5. TMS could induce transient changes in memory, attention and other cognitive functions. This is a theoretical risk but none of the safety studies conducted have found such side effects.

6. The effects of TMS on pregnancy are not know. Therefore, TMS is not performed on women who are pregnant or who are planning to become pregnant within the next 6-9 weeks.

7. Finally, even though TMS and the other techniques employed in this study have been used in several laboratories and clinical settings worldwide for many years, I am aware that there could be some unexpected complications.

I wish to voluntarily participate as a patient undergoing a course of Transcranial Magnetic Stimulation in which a trained practitioner, either Dr. Turell or one of his associates, will conduct Transcranial Magnetic Stimulation on me. I am familiar with the nature of the procedure and the risks of receiving Transcranial Magnetic Stimulation. I may change my mind at any time about continuing to receive Transcranial Magnetic Stimulation as a patient, though the antidepressant treatment effect of a reduced course of treatment may not be as robust. I understand that in the event of injury related to my participation in the Transcranial Magnetic Stimulation treatment program, I will be treated by Dr. Turell or his associates at the office, and if necessary, I will be sent to a hospital for further treatment.

I will not be compensated by Strive or by Dr. Turell or his associates. Reasonable Medical Treatment will be offered for injuries directly caused by my participation in the Program, for which my insurer or I will be billed at the usual charge. I hereby release Strive, Dr. Turell, and his associates from any and all liabilities and expenses related to my decision to receive TMS as part of my treatment of depression.

_____ Signature of Patient

_____ Printed Name of Patient

_____Date

_____Signature of Provider

_____ Printed Name of Provider

_____ Date