Lado Healing Institute

TMS Treatment – "What to Expect"

* **Initial Evaluation** (First Visit – plan visit to be at the office about 2-3 hours)
  - Full psychiatric evaluation: Includes online paperwork on the patient portal, computerized psychiatric assessment, urine drug screen, pregnancy test- if applicable, assessment with medical assistant (including depression screening, vital signs, review of medications, review of prior treatments and any other requirements by insurance for TMS approval) and then evaluation with Dr. Lado to review symptoms, diagnoses, and treatment options.
  - Genetic testing (Cheek Swab) is often done to provide us an in depth look at how you specifically metabolize or process medications. Having this information available helps determine medication choices, if needed. It also tests how your body converts folic acid into L-Methylfolate (the bio-available form of folic acid), which is important for TMS treatment success.
  - Blood work may also be ordered to check overall health, kidney/liver function, and hormones which may affect treatment options.
  - If the doctor deems that the patient is clinically appropriate for TMS treatment and all criteria for the patient's insurance are met for TMS then we will submit a benefits investigation and prior authorization to your insurance for coverage of the treatment.
    - If the insurance criteria hasn't been met, then the patient may choose to self-pay or will need to continue psychiatric treatment such as referral to therapist or trying anti-depressants or augmentation medications to meet the insurances criteria prior to moving on the TMS Treatment.

* **TMS Consult** (Usually second visit – about 45 minutes)
  - Will meet with TMS Coordinator to review procedure, financial responsibilities and assistance, get any information needed for prior authorization, go over any questions, and complete consent forms.

* **Treatment 1** (Usually third visit - about 2 hours)
  - Mapping and motor threshold determination
    - method used to find both the position and the amount of energy to be used in your treatment. If we can activate the nerve cells that tell your thumbs to move, then we can make the nerve cells that contribute to your depression and anxiety activate.
  - 1st full treatment will be done after the motor threshold determination
  - Scheduling for full treatment course should be completed on this day (sessions 1-30 will be 5 days a week for 6 weeks, the following 6 sessions will be tapered down over the next 2-3 weeks.)

* **Treatments 2-12, 14-22, and 24-30** (40 minutes)
  - Daily treatments Monday through Friday.
  - By treatment 10, the tolerability should be acceptable.

* **Approximately Treatment 13** (maybe 1-2 hours)
  - Scheduled follow up appointment with Dr. Lado. If necessary, make changes to treatment including possible re-determination of motor threshold.

* **Approximately Treatment 23** (maybe 1-2 hours)
  - Scheduled follow up appointment with Dr. Lado. If necessary, make changes to treatment.

* **Treatments 31-35** (40 minutes)
  - Will be tapered from daily to a couple times a week on week 7 and 8.

* **Treatment 36** (maybe 1-2 hours)
  - Final day of treatment and follow up appointment with Dr. Lado.

* **After Treatment:** (about 1 hour)
  - There will be a 2 and 6-week follow up appointments with Dr. Lado.

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Patient Name:

Date:

Patient Consent for a Medical Procedure- NeuroStar TMS Therapy

This is a patient consent for a medical procedure called NeuroStar TMS Therapy®. This consent form outlines the treatment that your 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 NeuroStar TMS Therapy.

The information contained in this consent form is also described in the Depression Patient's Manual for Transcranial Magnetic Stimulation with the NeuroStar TMS Therapy® System which is available from your doctor. Not all information in the Manual is stated here, so you should read the Patient Manual and discuss any questions that you have with your doctor. Once you have reviewed the manual and this consent form, be sure to ask your doctor any questions that you may have about NeuroStar TMS Therapy.

Dr. Lado has explained the following information to me:

a. TMS stands for "Transcranial Magnetic Stimulation". NeuroStar TMS Therapy is a medical procedure. A TMS treatment session is conducted using a device called the NeuroStar TMS Therapy System, 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. NeuroStar TMS Therapy is a safe and effective treatment for patients with depression who have not benefitted from antidepressant medications.

c. Specifically, NeuroStar TMS Therapy has been shown to relieve depression symptoms in adult patients who have been treated with prior antidepressant medications but did not get better.

d. The safety and efficacy of NeuroStar TMS Therapy has not been established in patients who did not take any antidepressants during this current period of depression.

e. During a TMS treatment session, the doctor or a member of their staff will place the magnetic coil gently against my scalp on the left front region of my head. The magnetic fields that are produced by the magnetic coil are pointed at a region of the brain that scientists think may be responsible for causing depression.

f. To administer the treatment, the doctor or a member of their staff will first position my head in the head support system. Next, the magnetic coil will be placed on the left side of my head, and I will hear a clicking sound and feel a tapping sensation on my scalp. The doctor will then adjust the NeuroStar TMS Therapy 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. How often my motor threshold will be re-evaluated will be determined by my doctor.

g. Once motor threshold is determined, the magnetic coil will be moved, and I will receive the treatment as a series of "pulses" that last about 4 seconds, with a "rest" period of about 26 seconds between each series. Treatment is to the left front side of my head and will take about 40 minutes. I understand that this treatment does not involve any anesthesia or sedation and that I will remain awake and alert during the treatment. I will likely receive these treatments 5 times a week for 4 to 6 weeks (20 to 30 treatments). I will be evaluated by the doctor regularly during this treatment course. The treatment is designed to relieve my current symptoms of depression.

h. During the treatment, I may experience tapping or painful sensations at the treatment site while the magnetic coil is turned on. These types of sensations were reported by about one third of the patients who participated in the research studies. I understand that I should inform the doctor or his/her staff if this occurs. The doctor may then adjust the dose or make changes to the where the coil is placed in order to help make the procedure more comfortable for me. I also understand that headaches were reported in half of the patients who participated in the clinical trial for the NeuroStar device. I understand that both discomfort and headaches got better over time in the research studies and that I may take common over-the-counter pain medications such as acetaminophen if a headache occurs.

i. The following risks are also involved with this treatment:

   The NeuroStar TMS Therapy System should not be used by anyone who has magnetic-sensitive metal in their head or within 12 inches of the NeuroStar magnetic coil that cannot be removed. Failure to follow this restriction could result in serious injury or death. Objects that may have this kind of metal includes:

   - Aneurysm clips or coils
   - Stents
   - Implanted Stimulators
   - Electrodes to monitor your brain activity
   - Ferromagnetic implants in your ears or eyes
   - Bullet fragments
   - Other metal devices or objects implanted in the head
   - Facial Tattoos with metal ink or Permanent makeup.

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

k. NeuroStar TMS Therapy is not effective for all patients with depression. Any signs or symptoms of worsening depression 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 depression.

l. Seizures (sometimes called convulsions or fits) have been reported with the use of TMS devices. However, no seizures were observed with use of the NeuroStar TMS Therapy system in over 10,000 patient treatment sessions in trials conducted prior to FDA clearance of the NeuroStar TMS System. Since the introduction of the NeuroStar TMS System into clinical practice, seizures have been rarely reported. The estimated risk of seizure under ordinary clinical use is approximately 1 in 30,000 treatments or 1 in 1000 patients.

m. Because the NeuroStar TMS Therapy system produces a loud click with each magnetic pulse I understand that I must wear earplugs or similar hearing protection devices with a rating of 30dB or higher of noise reduction during treatment.

n. I understand that most patients who benefit from NeuroStar TMS Therapy experience results by the fourth week of treatment. Some patients may experience results in less time while others may take longer.

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

p. I understand TMS may be used for off-label use at Dr. Lado's discretion such as in patients under the age of 18, diagnoses other than depression, maintenance treatment and other non-FDA approved treatments. Non-FDA approved treatment usually are not covered by the insurance policy.

q. Patients may need maintenance treatment after the initial course of treatment (maintenance treatment is defined as regular treatments deemed clinically necessary by Dr. Lado to maintain or improve the effectiveness of the original treatment). This usually is not covered by insurance.

I have read the information contained in this Medical Procedure Consent Form about NeuroStar TMS Therapy and its potential risks. I have discussed it with Dr. Lado who has answered all of my questions. I understand there are other treatment options for my depression available to me and this has also been discussed with me.

I therefore permit Dr. Lado and his staff to administer this treatment to me.

_______________________________ _______________________________

PATIENT SIGNATURE DATE

_______________________________ _______________________________

WITNESS DATE

Lado Healing Institute

Patient name:

Date:

Acknowledgement of Financial Responsibility for the Cost of Services

Re: NeuroStar TMS Therapy® I have been informed that my health care benefits insurer or administrator may determine that the above referenced service(s) may not be a covered service, may not be medically necessary, or medically appropriate as those terms are defined in my health care benefits plan. Therefore, the service would be excluded from coverage by my health care plan benefits. My provider has also informed me about alternative treatments, if any, that may be covered by my health care benefits plan. I understand that my provider may request my health care benefits plan reconsider determination by presenting evidence that the referenced service(s) is not an investigational service, is a covered service or the service is considered to be medically necessary or medically appropriate.

I also understand that I have the right to request reconsideration of that determination, as described in the member grievance section of my health care benefits plan, either before or after receiving the service(s). I have been informed that the potential costs of the referenced service(s) will be approximately $14,750.00 for a TMS treatment course including the TMS mapping, 36 TMS treatments, remapping, and 5 follow-up visits. I understand that, if I elect to receive the service(s) and my health care benefits plan determines that the service(s) is an investigational service, is not a covered service or the service is not considered to be medically necessary or medically appropriate, I will be responsible to pay for all costs associated with the service(s), including, but not limited to, practitioner costs, facility costs, ancillary charges and any other related expenses. I acknowledge that my health care benefits plan may not pay for the service(s). In the event of multiple procedures, this form is valid only for forty units of the prescribed service(s), unless specifically provided for otherwise.

I understand that any self-pay discount received will be the maximum out of pocket cost I will incur for the TMS treatments. If my insurance is billed, I understand that insurance payments will be applied to the full retail rate and any amount above that will be refunded or left as a credit for future visits, as I deem necessary. ***(Initial:_______)***

Signature of Patient: Date:

Witness: Date:

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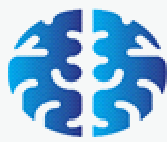
Lado Healing Institute

Patient Name: **Insurance Policy Number:**

Advance Beneficiary Notice of Non-coverage (ABN)

NOTE: If my Insurance doesn't pay for **D** below, I may have to pay.

Your Insurance does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect your insurance may not pay for the **D. Options** below.

D. Options:	E. Reason Insurance May Not Pay:	F. Estimated Cost:
Urine Drug Screen	Non covered procedure	$30.00
M.I.N.I. Neuropsychiatric Interview	Non covered procedure	$80.00
Urine Pregnancy Test	Non covered procedure	$10.00
TMS Mapping	Non covered procedure	$455.00
TMS Treatment	Non covered procedure	$385.00
TMS Remapping	Non covered procedure	$455.00
Patient cancellation w/o 24 hours notice before your visit	Non covered procedure	$50.00

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D** listed above

G. OPTIONS: Check only one box. We cannot choose a box for you.

❑ **OPTION 1.** I want the **D** listed above. Lado healing Institute may ask to be paid now, but I also want my insurance billed for an official decision on payment. I understand that if my insurance doesn't pay, I am responsible for payment on the day service is rendered. If my insurance does pay, Lado Healing Institute will refund any payments made, less co-pays or deductibles.

❑ **OPTION 2.** I want the **D** listed above, but do not bill my insurance. You may ask to be paid now as I am responsible for payment. **I cannot appeal if my insurance is not billed.**

❑ **OPTION 3.** I don't want the **D** listed above. I understand with this choice I am **not** responsible for payment, and **Dr. Lado will not be able to proceed with my care.**

H. Additional Information: The test listed above is necessary as part of your treatment and evaluation.

This notice gives our opinion, not an official insurance decision. Signing below means that I have received and understand this notice. You also receive a copy. If you have question on Medicare Billing, call 1-800-633-422.

I. Signature of Patient or Parent/Legal Guardian:

	J. Date:

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Consent or Refusal to Wear Hearing Protection

for the Duration of TMS Therapy

I ____________________________, have been fully informed of the potential for hearing function loss to include possible damage to the inner ear structures and nerves associated with hearing. I have been fully advised of the need for hearing protection during TMS Therapy.

Please check one of the following:

- ☐ I have been offered and agree to wear adequate hearing protection (NRR 30db) at all times while undergoing TMS Therapy.

- ☐ I have been offered hearing protection and decline to use it as this time or at a future time during the TMS treatment. This will allow you to use ear plugs or noise reduction devices at your own discretion.

____

Printed Name   Date of Birth

____

Patient Signature   Date

____

Witness Signature   Date

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Lado Healing Institute

Authorization for Use and Disclosure of Protected Health Information under HIPAA RULE164.508

Do you want a copy of your medical record? ____NO ___ YES

I _____________________________________ authorize **Leonard A. Lado MD d/b/a Lado Healing Institute** recieve and/or disclose in any form of print, secure e-mail or patient portal a copy of records concerning Individual **but only as follows:**

____ Family ____ Patient or Guardian ____Agency ____Health Care Professional ____Attorney

Full Name of recipient: _____________________________ Fax: ______________ E-mail: _______________________

Address of recipient: _______________________________ City: ______________ State: ______ Zip Code: ______

For the purpose(s) ONE OF THE FOLLOWING: (please check all apply)

Phone:_____________________________

Second Fax: ______________________

_____ DISABILITY EVALUATION

_____ COURT OR LEGAL MATTERS

_____ TO REVIEW MY OWN RECORDS (FLORIDA STATUE 45 CFR 164.512)

_____ CONTINUITY OF CARE

_____ OTHER: ____

I specifically authorize you recieve and/or disclose the following types of super-confidential information
Please initial all of the following:

__________ HIV RECORDS (INCLUDING HIV TEST RESULTS) AND SEXUALLY TRANSMISSIBLE DISEASES

__________ ALCOHOL AND SUBSTANCE ABUSE DIAGNOSIS AND TREATMENT RECORDS

__________ PSYCHOTHERAPY RECORDS (FLORIDA STATUE 45 CFR 164.512)

__________ TUBERCULOSIS

__________ PSYCHIATRIC EVALUATION AND PSYCHOLOGICAL TESTING

__________ PHARMACOGENETIC RESULTS

__________ LAB RESULT

__________ PSYCHIATRIC PROGRESS NOTE

I specifically authorize you to recieve and/or disclose the following Protected Health Information.
Please initial all of the following:

__________ WRITTEN MEDICAL RECORDS

__________ X-RAYS/MRI/CT

__________ BILLING RECORDS

__________ PRESCRIPTION RECORDS

__________ OTHER *(specify in detail the description of other protected information}:* ___________________________

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I understand that my records may be subject to re-disclosure by recipient(s) and unprotected by federal or state law; that this Authorization remains effective until 1 YEAR OF THE DATE OF SIGNATURE; the following event.

- ☐ Gunshot Wounds and Life-Threatening Injuries
- ☐ Suspected Child Abuse
- ☐ Suspected Vulnerable Adult Abuse
- ☐ Sexual Battery
- ☐ Deaths
- ☐ Public Health Surveillance
- ☐ Disclosures to Law Enforcement
- ☐ Worker's Compensation

The Privacy Rule permits health care providers to comply with court orders or court-ordered warrants, subpoenas or summons, grand jury subpoenas, and administrative summons or civil investigative demands. (45 CFR 164.512(f)(1)(ii)).

Until you actually receive a signed revocation or until the records retention period required under federal and FLORIDA 45 CFR 164.512 law has expired, whichever first occurs; that I have been given an opportunity to ask questions; that I have received a copy of the signed Authorization; that I may inspect a copy of my protected health information to be used or disclosed under this Authorization; that you have not conditioned provision of services to or treatment of me upon receipt of this signed Authorization; and that I may refuse to sign this Authorization. My refusal to sign will not affect my eligibility for benefits or enrollment, payment for or coverage of services, or ability to obtain treatment, except as provided on this form. If the purpose of this Authorization is for the use and/or disclosure of health information for a research study, and I refuse to sign this Authorization, you reserve the right to deny treatment associated with such research. If the purpose of this Authorization is to disclose health information to another party based on health care that is provided solely to obtain such information, and I refuse to sign this Authorization, you reserve the right to deny that health care. I understand that I may inspect or copy the information that is used or disclosed. I understand that I may revoke this Authorization at any time by notifying you in writing, except to the extent that action has been taken in reliance on this Authorization; or if this Authorization is obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

{Please check only one}

Full Name of ____Patient or _____Parent/Guardian: ________________________ Date of Birth: _____________

Patients Phone: _________________________

Signature of Patient or Parent/Guardian: _________________________________ Date of Sign: ______________

Medical release forms are active for one year from the date sign. If you would like the authorization to be for a time shorter than that you may indicate when you would like it to end here: ________________________

(A copy of this signed form will be provided the individual at the patients request)

Signature of Staff as Witness: ____ Date of Sign: ______________

Lado Healing Institute

Authorization for Use and Disclosure of Protected Health Information under HIPAA RULE164.508

Do you want a copy of your medical record? ____NO ___ YES

I ____________________________________ authorize **Leonard A. Lado MD d/b/a Lado Healing Institute** recieve and/or disclose in any form of print, secure e-mail or patient portal a copy of records concerning Individual **but only as follows:**

____ Family ____ Patient or Guardian ____Agency ____Health Care Professional ____Attorney

Full Name of recipient: ____________________________ Fax: ______________ E-mail: ______________________

Address of recipient: ______________________________ City: ______________ State: ______ Zip Code: ______

For the purpose(s) ONE OF THE FOLLOWING: (please check all apply)

Phone:_____________________________

Second Fax: ______________________

_____ DISABILITY EVALUATION

_____ COURT OR LEGAL MATTERS

_____ TO REVIEW MY OWN RECORDS (FLORIDA STATUE 45 CFR 164.512)

_____ CONTINUITY OF CARE

_____ OTHER: ____

I specifically authorize you recieve and/or disclose the following types of super-confidential information
Please initial all of the following:

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__________ TUBERCULOSIS

__________ PSYCHIATRIC EVALUATION AND PSYCHOLOGICAL TESTING

__________ PHARMACOGENETIC RESULTS

__________ LAB RESULT

__________ PSYCHIATRIC PROGRESS NOTE

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Please initial all of the following:

__________ WRITTEN MEDICAL RECORDS

__________ X-RAYS/MRI/CT

__________ BILLING RECORDS

__________ PRESCRIPTION RECORDS

__________ OTHER *(specify in detail the description of other protected information}:* ________________________

US-02302BG-FORM 1.0

I understand that my records may be subject to re-disclosure by recipient(s) and unprotected by federal or state law; that this Authorization remains effective until 1 YEAR OF THE DATE OF SIGNATURE; the following event.

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- ☐ Suspected Child Abuse
- ☐ Suspected Vulnerable Adult Abuse
- ☐ Sexual Battery
- ☐ Deaths
- ☐ Public Health Surveillance
- ☐ Disclosures to Law Enforcement
- ☐ Worker's Compensation

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{Please check only one}

Full Name of ____Patient or _____Parent/Guardian: ________________________ Date of Birth: _____________

Patients Phone: _________________________

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(A copy of this signed form will be provided the individual at the patients request)

Signature of Staff as Witness: ____ Date of Sign: ______________