



**NEUROMODULATION TECHNIQUE  
RESEARCH SUBJECT  
INFORMED CONSENT FORM**

**Protocol Title:** A Study of the Efficacy of NeuroModulation Technique with Children Diagnosed with Autism

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**NMT Site Investigator:** \_\_\_\_\_  
\_\_\_\_\_  
[fill in the name, clinic address and phone number  
of your local NMT researcher]

**Why am I being asked to participate in this study?**

You are being asked to give permission for your child to participate in a research study since your child meets the requirements for enrollment into this study. Your child's participation is voluntary, which means you can choose whether or not you want your child to participate. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you and your child will have to do in this study. A member of the research team is going to talk to you about the research study, and he or she will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. If you find any of the medical language difficult to understand, please ask your research team member about this form. If you decide to participate, you will be asked to sign this form, giving consent for your child to be in the study.

**What is the purpose of this research study?**

Your child has been previously diagnosed by a physician or psychologist as having the symptoms of autism. You have been invited to participate in a research study to determine the effectiveness of

NeuroModulation Technique (NMT) in reducing the symptoms of your child's autism.

NeuroModulation Technique is not a medical or psychological diagnostic procedure and does not diagnose disease. NMT, however, does determine the patient's perception of conditions contributing to illness.

The human nervous system is a very sophisticated "bio-computer" that can be thought of as having a voluntary/conscious control system as well as an autonomic/unconscious control system. Illness may result from confusion within the body's nonconscious internal control center, referred to in NMT as the Autonomic Control System (ACS). According to this model, illness may represent faulty or incomplete information that the ACS has been using to regulate body functioning.

Since the ACS represents the body's nonconscious internal control center, some type of communication with the ACS is needed in order to find out what type of information or corrections the ACS may need in order to function more effectively. NMT uses Muscle Response Testing (MRT) to allow the NMT practitioner to communicate with the Autonomic Control System of the patient in order to detect ACS errors. For the purposes of this study, the NMT researcher will use NMT to detect any ACS errors that may be contributing to autistic behavior or any associated health conditions that may be contributing to autistic symptoms. MRT employed in NMT may not be 100% accurate, but sufficient information is gathered from MRT for purposes of the NMT treatment.

Once Autonomic Control System errors are detected using MRT, the NMT practitioner then applies corrective statements that direct the ACS to more optimal functioning. These corrective statements may be delivered audibly or silently. After each such corrective statement, the NMT Practitioner applies a gentle stimulation to the body while the patient engages in certain breathing cycles. This process helps insure a more durable correction. The types of stimulation that may be used include gentle tapping of the spine, head, hands, feet, ears, or other areas using one's hand, a massage roller instrument, or by other means such as a light directed on the body.

NMT patients range from babies only weeks old to patients in their 80's and 90's. NMT is non-invasive, non-force, and completely painless. NMT is completely compatible with any other type of health care a person may be receiving.

If your child is not able to participate in the Muscle Response Testing and treatment for any reason, your NMT researcher may perform the MRT and corrective statements on you or another person in the room (with your permission) as a surrogate for your child. The researcher may also choose to do self-MRT as a surrogate for your child. A surrogate acts as a substitute for the person who is not able to be muscle tested him or herself. You may hold or touch your child while the researcher performs MRT on you - the intention of the NMT researcher during MRT is always to query or communicate with the Autonomic Control System of your child. You can still serve as a surrogate for your child even if he or she doesn't want to be held or touched. Think of the process of being a surrogate with the analogy that the surrogate is holding up a phone to your child's ear (ACS) versus the child holding the phone him or herself. The communication is still with the ACS of your child in both cases, but you help the process when you serve as a surrogate.

Your child need not have any direct contact with your NMT researcher, but your child is still required to come to each NMT session. Your child will receive the same benefits of NMT treatment whether your child receives the MRT and corrective statements directly or whether a surrogate is used.

### **How long will my child be in the study? How many other people will be in the study?**

We expect your participation to last approximately 8 weeks. The entire study is expected to last approximately 15 weeks in order to enroll all subjects. A total of fifty-eight children from 24 different research sites will be invited to participate.

### **Eligibility:**

Fifty-eight children between the ages of 5 through 10 years of age will be recruited from 24 different study sites. Both boys and girls are eligible for the study.

### **Inclusion Criteria:**

Qualified participants are those who have received a formal diagnosis of autism from a physician or psychologist using DSM-IV, DSM-IV-TR or ICD-9-CM diagnostic criteria. Parents and/or legal guardian must supply written proof of the autism diagnosis. Autism (DSM-IV, DSM-IV-TR or ICD-9-CM 299.0) **must** be diagnosed - any other diagnosis such as Pervasive Developmental Disorder (PDD), Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS) or Asperger Syndrome is **not** sufficient for inclusion in this study.

Children must have had their diagnosis of autism for at least one year prior to the date of the application for participation in this study. Children must not have started any new therapies or stopped any ongoing therapies designed to treat their autism such behavior therapy, speech therapy, physical therapy, sensory integration, dietary modification or dietary supplementation, or any alternative or experimental therapies not mentioned in this list in the 6 months prior to the date of the application for participation in this study.

If accepted into this study, the child must continue with the same therapies to treat autism that he or she has been on at the time of the application for participation in this study and must not start any new therapies besides the NMT until the conclusion of this study. The purpose of this requirement is to ensure that improvement in autistic symptoms during the course of this study is not due to stopping a therapy that may have caused a worsening of symptoms in the child, and to make sure that improvement seen during the course of this study was not due to a therapy that was recently started prior to receiving NeuroModulation Technique.

**Once accepted into the study and during the entire course of this study, children will be required to continue with any therapies they have been receiving prior to starting the study, and they will be required to not start any new therapies besides NeuroModulation Technique during the course of this study.**

**Children in the study will be allowed to make any medication or dietary changes during the course of the study *if required by their treating pediatrician.***

## **Exclusion Criteria:**

Excluded from participating will be children with any of the following medical conditions: cerebral palsy, Down's syndrome, traumatic brain injury, encephalitis, Lyme disease, cancer, any active infectious disease, endocrine disorder, other mental disorders such as psychotic disorders or other mood disorders including bipolar disorders, or any acute, chronic or unstable medical condition (such as a seizure disorder, Crohn's disease, asthma, bronchitis, etc.) other than autism for which the child has been receiving treatment, medication and/or therapy. Also excluded from the study are children who have undergone chelation therapy in the past or are currently undergoing chelation therapy, and children who have displayed significant self-injurious behavior (children who have caused visible harm to themselves.) Children with a history of mild to moderate food or airborne allergies, sensitivities, or mild digestive problems are eligible to participate in the study. If you are not sure whether or not your child is eligible due to a medical condition that is not listed above, please have your participating NMT researcher contact the Study Chair, Dr. Robert Weiner, to see if your child will qualify to be in the study.

In order to participate in the study, children must not have received any previous NeuroModulation Technique treatment.

Parents and/or legal guardians of children in the study must be fluent in English and complete all forms and questionnaires in English (for U.S. and Canadian research sites only).

Based on the clinical judgment of the researchers or Study Chair, parents and/or legal guardians may be asked to withdraw their children from the study should the child miss two or more NeuroModulation Technique sessions, or should the parents and/or legal guardians fail to complete in a timely manner (more than one week late) required symptom checklists or behavioral inventories. **If a child misses an NMT session due to illness or any other reason, he or she must make up that session the same week or the following week.**

## **What am I being asked to do?**

### **Prior to study:**

Parents and/or legal guardians who are interested in having their children participate in this study will contact an NMT research participant to receive an application to participate in the study. This application will include an application form, consent form including a videotape release (this form), and the Autism Treatment Evaluation Checklist (ATEC). Parents will return these completed forms to the NMT research participant by a deadline specified in the application form. The names of all children at each research site who meet the selection criteria for the study will be placed in a selection pool. Two names will be drawn at random from this selection pool at each research site for inclusion in the study.

### **During the Study:**

#### **Tests and Questionnaires**

Questionnaires and Behavior Rating Forms: Pre-Treatment Symptom Questionnaire for Children (15 - 20 minutes to complete), Autism Treatment Evaluation Checklist (ATEC) (5 – 10 minutes to complete), Aberrant Behavior Checklist (ABC) (5 – 10 minutes to complete), Pervasive Developmental Disorder Behavioral Inventory (PDDBI) (30 – 45 minutes to complete) and Post-

Treatment Symptom Questionnaire for Children (15 - 20 minutes to complete).

### **Procedures**

NeuroModulation Technique: See description of NMT on Page 1 and 2 of this form in the section, “What is the purpose of this research study?” Each NMT session will last between 45 and 60 minutes. Participation in this study will take your child up to a total of 12 hours (12 NMT sessions). While both parents or both legal guardians are required to sign this consent form, only one parent is required to accompany his or her child to each of the 12 NMT sessions. Your participation will also include the time it takes to complete the above-mentioned questionnaires and rating forms.

### **Schedule for Participants:**

If you give consent for your child to be in this study, the following will happen. The first child drawn from the selection pool (“Child 1”) will receive 12 sessions of NMT, 2 sessions a week for 6 weeks at your NMT researcher's office. The second child drawn from this selection pool (“Child 2”) will serve as the wait-list control, and will not receive any NMT until 2 weeks after the first child has completed his or her 12 NMT sessions. At this time, the second child will receive 12 sessions of NMT, 2 sessions a week for 6 weeks at your NMT researcher's office.

Week 1: Once two names are drawn from the selection pool, parents of Child 1 and Child 2 will complete the Symptom Questionnaire for Children (Part 1 & 2), ATEC, ABC and the PDDBI.

Week 2: Child 1 receives sessions 1 & 2 of NMT

Week 3: Child 1 receives sessions 3 & 4 of NMT

Week 4: Child 1 receives sessions 5 & 6 of NMT

Week 5: Parent of Child 1 completes the ATEC and the ABC prior to the start of session 7. Child 1 receives sessions 7 & 8 of NMT.

Week 6: Child 1 receives sessions 9 & 10 of NMT

Week 7: Child 1 receives sessions 11 & 12 of NMT

Week 8: Parent of Child 1 completes ATEC, ABC, PDDBI and Symptom Questionnaire for Children (Part 2). Parent of Child 2 completes ATEC, ABC, PDDBI and the Symptom Questionnaire for Children (Part 1 & 2).

Week 9: Child 2 receives sessions 1 & 2 of NMT.

Week 10: Child 2 receives sessions 3 & 4 of NMT.

Week 11: Child 2 receives sessions 5 & 6 of NMT.

Week 12: Parent of Child 2 completes ATEC and ABC prior to session 7. Child 2 receives sessions 7 & 8 of NMT.

Week 13: Child 2 receives sessions 9 & 10 of NMT

Week 14: Child 2 receives sessions 11 & 12 of NMT

Week 15: Parent of Child 2 completes ATEC, ABC, PDDBI, and Symptom Questionnaire for Children (Part 2).

### **What are the benefits of participating in the study?**

Your child will receive the benefit of a detailed evaluation of his or her autistic symptoms in order to monitor any changes in symptoms as a result of participating in the study. Your child may experience the relief or improvement of his or her autistic symptoms including the reduction of negative or maladaptive behaviors (outbursts may decrease, poor or absent language or socialization may improve, etc.) and the increase of positive or adaptive behaviors (better overall health functioning, reduction of allergies and food sensitivities, improved digestive functioning and improved speech, communication and socialization skills).

Your child's participation in this study may benefit other patients with this disorder. However, it is possible that your child may not receive any benefits from participating in this study.

### **What are the possible risks or discomforts?**

Certain adverse effects may result from the treatment. These could include, but are not limited to, a temporary flare-up of your child's behavioral or physical symptoms. Other possible side effects include symptoms of heightened immune function or detoxification such as fever, chills, headache or body aches. Generally, any temporary flare-ups seen during the course of NMT treatment are short lived and are followed by a decrease in symptoms and an improvement in overall functioning.

Changes in behavioral or physical symptoms during the course of NMT treatment may also be totally unrelated to the NMT itself. For example, your child could catch a cold or the flu from exposure at home, school or when out in public, reactions to events outside the researcher's office could create emotional and/or behavioral changes, behaviors and physical symptoms seen during the course of this study may be a continuation of symptoms the child was experiencing before entering the study, etc.

### **What other choices do I have if my child does not participate?**

You have the right to decide that you do not wish your child to participate in this study. The decision to not allow your child to participate in this study will not affect your child's rights to receive any other service to which he or she is otherwise entitled.

There may be other autism treatments available to your child that he or she is not currently receiving. Please discuss this matter with your child's treating doctor about what additional therapies, if any, may be available to treat your child's autism.

### **Will my child be paid for being in this study?**

You or your child will not be paid for your child's participation in this study.

**Will I have to pay for anything?**

All study-required procedures including NMT therapy and the study assessment questionnaires will be provided without charge to you.

**What happens if my child is injured or hurt during the study?**

In the event you believe that your child may have suffered any physical injury as the result of your child's participation in this research study, you may contact the Study Chair listed on Page 1 of this form who will review the matter with you.

If your child has an illness or injury during this research trial that is not directly related to your child's participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

**When is the study over? Can my child leave the study before it ends?**

This study is expected to end after all participants have completed all visits, and all information has been collected. The participation of your child in this study may also be stopped at any time without your consent because: 1. The Study Chair or your NMT researcher feels it is necessary for your child's health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision. 2. You have not followed study instructions: A. The child has failed to show for any of the 12 NeuroModulation Technique sessions. Any missed appointments must be made up by the end of the week following the missed appointment. If a child misses two NMT sessions or fails to make up a single missed appointment by the end of the following week, he or she will be dropped from the study with no appeal. B. You have failed to complete in a timely manner (more than one week late) required symptom checklists or behavioral inventories; C. During the course of this study your child has started a new therapy for his or her autism (besides the NMT), or your child has stopped an ongoing therapy he or she was receiving in the 6 months prior to the date of the application for participation in this study; D. It is discovered that your child does not meet the eligibility criteria to participate in the study.

If you decide not to continue your child's participation in the study, you are free to withdraw your child from the study at anytime. You will be informed of any changes during the course of the study that might affect your decision for your child to continue in the study. You have the right to ask questions concerning the study before the study begins, during the study, and after the study concludes.

**Who can see or use my child's information? How will my child's personal information be protected?**

The Study Chair and research staff involved with the study will keep all personal health information collected for the study strictly confidential. All records will be coded and kept in locked files so that only the research team has access to them. No individual names will be used in any reports or publications resulting from this study.

Participation in research may involve a loss of privacy. Your child's research will be handled as confidentially as possible within the law. If instances of abuse or soon-to-occur physical injury of self or another person are discovered, they will need to be reported, as required by law. A court of law may also order release of confidential information.

**Who can I call about my child’s rights as a research subject?**

This document explains your child’s rights as a research subject. If you have questions regarding your child’s participation in this research study or if you have any questions about your child’s rights as a research subject, please talk to your NMT researcher, or you may contact the Study Chair listed on Page 1 of this form.

**Questions**

Your NMT researcher whose signature is below has explained this study to you and your questions were answered. If you have any other questions about the study, you may call your NMT researcher at \_\_\_\_\_[fill in with your NMT researcher's phone number].

*Participation in research is voluntary.* When you sign this form, you are giving consent for your child to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to allow your child to participate in this study. If you wish to have your child participate in this study, both parents or legal guardians should sign this form on the lines provided below. If you are legally a single parent and have court-granted authority to make independent health care decisions for your child, please indicate next to your signature. Your signature also means that you are permitting the Study Chair and the research staff to use personal health information collected about your child and your child’s family medical history (such as questions asking about the mother's health during pregnancy, and questions asking if there is a history of medical, language, learning or psychiatric problems in the child's immediate or extended family) for research purposes. If you have read this form and have decided to participate in this study, please understand that your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without jeopardy to any other treatments your child is otherwise entitled.

You have been given a copy of this consent form to keep.

\_\_\_\_\_  
Name of Subject/Child (Please Print)

\_\_\_\_\_  
Name of Parent or Guardian      Relationship to Child      Signature      Date  
Granting Consent (Please Print)

\_\_\_\_\_  
Name of Parent or Guardian      Relationship to Child      Signature      Date  
Granting Consent (Please Print)

\_\_\_\_\_  
Name of NMT Researcher Obtaining Consent      Signature      Date

## Consent to videotape

We are asking for your permission to allow us to videotape each individual treatment session as part of this research study.

The recordings will be used for analysis by the research team and for possible use as an educational teaching tool for those who are not members of the research team (for example, at conferences and symposiums on autism and/or NMT).

The recordings will not include any identifying information of you or your child's name. Portions of each video recording may include full facial/body pictures of you and/or your child.

The recordings will be stored in a locked file cabinet and labeled with a code linked to your child's identity. The original videotapes or copies of these videotapes will be sent to Dr. Robert Weiner, the Study Chair, who will keep the videotapes in a locked file cabinet. The videotapes may be retained indefinitely by the research team.

Your signature on this form grants the investigator(s) named above permission to videotape you as described above during participation in the above-referenced study. The investigators will not use the recordings for any other reason than those stated in this consent form without your written permission.

### **I (we) give consent to have each NMT treatment session videotaped:**

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Name of Parent or Guardian Granting Consent (Please Print)	Relationship to Child	Signature	Date
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Name of Parent or Guardian Granting Consent (Please Print)	Relationship to Child	Signature	Date
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