

INFORMED CONSENT DOCUMENT

CHILD ASSENT TO PARTICIPATE IN RESEARCH

**Efficacy of External Trigeminal Nerve Stimulation (TNS) for Treatment
of ADHD**

NCT05374187

09/29/2025

University of California, Los Angeles

CHILD (AGE 7-12) ASSENT TO PARTICIPATE IN RESEARCH

“TNS & ADHD”

1. My name is Dr. Loo or Dr. McGough (or Dr. Dillon).
2. We are asking you to take part in a research study because we are trying to see if a treatment called TNS helps children who have problems with attention and hyperactivity.
3. If you agree to be in this study we will ask you to use a small device called a TNS System that stimulates nerves on your head when you sleep each night. You will do this every night for 4 weeks. We may also call your parent once a week so that we can see how you are doing and take care of any problems that might come up.

Some participants in this study will get one of two levels of stimulation from the TNS system. We do not know which level of stimulation will help with attention and behavior problems. We are doing the study to try to figure this out.

Each week we will ask your parent some questions and ask your parent to fill out some forms. We will also ask your teachers to fill out some forms about how you are doing at school. At two of the visits we will put a cap on your head and measure the electricity in your brain, a procedure we call an EEG. While you are wearing the EEG cap, we will have you do some simple tests on a computer. The cap might be a little itchy or uncomfortable, but we do not expect you to have any risks or dangers from being in the study. In addition to the EEG, we will ask you to do some of the things you might do in school, like reading, math and spelling. We will also be asking you questions about your feelings.

4. Sometimes TNS can make your face or head feel strange, and might even be a little painful. We will make adjustments so this will not be a problem. Some patients feel some numbing or tingling on their heads or in their teeth. Some get headaches. Sometimes a rash can develop on your forehead where you place the strips. You might feel funny or get a little

embarrassed by questions we ask. You might also get tired, bored, or anxious when doing the computer tests.

It is important that you keep the TNS system safe and away from other children at home. Do not share your device with others.

5. There is a chance that this study will help improve your problems with attention or hyperactivity, and this might help you do better at school and home. There is also a chance that you will not improve.

We will give your parents \$25 for every visit you come to UCLA. You should get at least some or all of that money, depending on what your parent decides.

If TNS helps your attention, you and your parents can decide to continue receiving treatment for an additional 3 months.

6. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say “yes” you can still decide not to do this.

7. If you don’t want to be in this study, you don’t have to participate. Remember, being in this study is up to you and no one will be upset if you don’t want to participate or even if you change your mind later and want to stop.

8. You can ask any questions that you have about the study. If you have a question later that you didn’t think of now, you can call me at 310-825-9204 or ask me next time.

9. Signing your name below means that you agree to be in this study. Your doctors will continue to treat you whether or not you participate in this study. You and your parents will be given a copy of this form after you have signed it.

Name of Participant

Date