Title:
Screening for Autism Spectrum Disorders Using Auditory Brainstem Responses

Number: NCT03971578

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Project Funded by NIH NIDCD SBIR Grant R43DC018430-01 to Intelligent Hearing Systems Corp.

Grant Title:
Screening Device for Autism Spectrum Disorders using High Stimulation Rate ABR with Continuous Loop Averaging Deconvolution

INFORMED CONSENT FORM

STUDY INFORMATION:
Title: How Children With and Without Autism Process Sounds
Principal Investigator: Christine Delgado, Ph.D.
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Sponsor: This research study is supported by a grant (1R43DC018430-01) from the National Institutes of Health (NIH), National Institute on Deafness and Other Communication Disorders (NIDCD) to Intelligent Hearing Systems.

PURPOSE: The goal of this study is to measure brain responses in children while they listen to click sounds. The ways in which children's brains respond to these sounds may be linked to developmental disorders, such as autism.

ELIGIBILITY: We will study children with autism and children without autism. Your child must be healthy and between the ages of 1.5 and 5.5 years old.

PROCEDURE: During your visit, you will be asked to provide us with information about your child and your family. You will also be asked questions about your child's development. We will measure the size of your child's head using a measuring tape. We will also conduct two tests on your child that are very similar to the hearing test your child most likely received in the hospital shortly after he/she was born. First, we will give your child a routine hearing test that involves placing earphones in his/her ears. If your child's hearing is normal, we will conduct another test. This second test involves placing earphones in your child's ears and small stickers called "electrodes" on your child's head. Sounds will be played through the earphones and the electrodes will measure brain activity in response to those sounds. Both tests are painless and require that the child be quiet and lie still. If you choose, your child can watch a silent video or participate in some other quiet/calm activity during this time. You will be with your child for the entire duration of your visit. The study is designed to be completed in one session, but if this is not possible you may be asked to return for a second session. The two tests should take no more than 30 minutes and the total session should take about 90 minutes.

RISKS: The risks of being in this study are minimal. The equipment and procedures have been used in previous studies with human children and adults with no negative effects. The devices that will be used on your child have been tested for safety and are approved by the U.S. Food and Drug Administration (FDA). There are no known side effects, risks, or complications associated with these tests. Rarely a skin rash or irritation may occur where the stickers were placed on the skin.

BENEFITS: Test results pertaining to the hearing status of your child will be provided to you. The overall findings of the study will provide information about brain activity in children with autism that may be used to develop and improve screening tests for

newborns. If we can find out that a child is at risk for autism or another developmental disability when they are first born, then this may lead to better support for these children. If you would like, after the study is finished, we will share with you our findings.

COSTS: You may have transportation costs for being in this study. You will not receive compensation for transportation in this study.

PAYMENT TO PARTICIPANT: If you agree to be in this research study, we will pay you $50.00 at the completion of the study for your time and effort. We will give you a partial payment for an incomplete visit if you do not return to complete the study.

CONFIDENTIALITY: Data collected for this study will be accessed and analyzed by collaborators at the University of Miami, Harvard University, and Intelligent Hearing Systems. The NIH is funding this study and may, therefore, request to review and obtain copies of your records. Your records may also be reviewed for audit purposes by authorized University of Miami employees or other agents who will be bound by the same provisions of confidentiality. Any data from the study provided to other entities or presented/published will be in aggregate/summary form and will not include any identifying information. Paper forms will be stored in a locked file cabinet and electronic information and data will be stored in a secure, encrypted data storage platform that is password protected. Data analyses will be conducted using a de-identified database (i.e., all names and identifying information will be removed).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you or your child. At most, the web site will include a summary of the results. You can search this web site at any time.

SHARING INFORMATION: Families who participate in our study may be interested in participating in other research projects at the University of Miami. Please indicate below if you would like for us to provide your contact information to researchers conducting other studies that you and/or your child may be eligible to participate in.

[ ] Yes, I give permission to share my contact information.

[ ] No, I do not wish to share my contact information.

RIGHT TO WITHDRAW: Your participation is voluntary. That means you can decide that you do not want you or your child to be in the study. Once you begin, you can request to stop any procedure at any time. You can decline to answer or skip any question you do not wish to answer. No consequences will result from either declining or discontinuing participation. Upon request, we will give you a copy of this consent form.
QUESTIONS: Ask us questions now or at any time during your visit(s). Talk to the research team if you have questions, problems, concerns, or complaints, want more information, want to offer a suggestion, think you or your child has been injured, or

would like a copy of the results. You can contact Dr. Christine Delgado at 305-284-3371 or by email at cdelgado@umiami.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs. Please call the HSRO at 305-243-3195 if you are a participant in any research being conducted at UM and:

- Your questions, concerns, or complaints are not being answered by the research team
- You cannot reach the research team
- You want to talk to someone besides the research team
- You have questions about your rights as a research participant
- You want to get information or provide input about this research

PARTICIPANT'S (PARENT'S) STATEMENT/SIGNATURE:

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.
- I agree to my child being in the research study described above.
- I will receive a copy of this consent form after I sign it, upon request.

_____
Printed Name of Child

_____
Printed Name of Parent/Legally Authorized Representative

_____ _____
Signature of Parent/Legally Authorized Representative Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date