Informed Consent Form

Study Title: Project VOICES: Vocal Optimization in Children Elevating the Spectrum

NCT Number: NCT06875843

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VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Jena McDaniel, PhD, CCC-SLP **Revision Date: 2025-03-04**
Study Title: Project VOICES (Vocal Optimization in Children Elevating the Spectrum)
Institution/Hospital: Vanderbilt University Medical Center

Name of participant: _____ Age: _____

Greetings, thank you for your interest. This form tells you about our research study. Please read carefully. We are happy to answer any questions. You will be given a copy of this consent form.

Key Information:

- This project is studying how to improve vocalizations in children with autism to help them learn to talk.
- Participation of you and your child is completely voluntary. You and your child may stop at any time.
- Your child's participation will take about 20 minutes per session, about three times per week, for about 6 to 8 weeks. All sessions will be video recorded.
- You will be asked to complete a few questionnaires about your child and the study procedures.
- The only anticipated risks are fatigue / boredom and breach of confidentiality. These risks of fatigue / boredom do not exceed those experienced within an educational setting. All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed.
- Your child may benefit from participation by using more vocalizations and/or words. Participation may also help us learn the best ways to teach children with autism to learn to talk.

Detailed Information:

Why are we doing this research and why are you asked to participate?
Your child is being asked to take part in this research study because your child has autism or has possible signs of autism, is 2 to 5 years old, and is not yet talking or just beginning to talk. We know that many children with autism take longer to learn to talk than children without autism. We want to learn more about how to help children with autism learn to talk. You are being asked to take part to provide some information about your child and the study procedures to help us develop strategies to teach children to talk.

Do you have to be in this research and can you stop if you want to?
You do not have to be in this research study, and you can stop being in this study at any time. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want your child to be in this study.

What will you do and how long will it take?
Eligibility Evaluation
If you choose for your child to participate, we will first complete a speech-language evaluation and an autism evaluation (if one has not been completed) to determine whether your child is eligible to participate. The evaluation is expected to take 2 to 2.5 hours and can be completed in two or more sessions if your child gets

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tired or if that is more convenient for you or your child. We will also ask you to provide demographic (e.g., age and sex), hearing, and vision information about your child and to complete a checklist of the words your child understands and says. These forms take about 30 minutes to complete.

Individuals who are eligible for the study will be invited to participate in the intervention. Those who are not eligible will not be asked to participate. All individuals receive their evaluation results, regardless of eligibility.

Vocalization Intervention

The intervention focuses on increasing the number of vocalizations that your child makes. We respond to your child's vocalizations in specific ways and use certain developmentally appropriate toys and turn-taking games to increase how often your child makes sounds. We see how often your child vocalizes in three different conditions to determine which factors matter. We also look at how complex your child's vocalizations are. The interventionist is a trained research team member, such as a speech-language pathologist.

1. Contingent responses condition: The interventionist imitates your child. They offer more complex responses when your child produces more complex vocalizations. For example, the interventionist will add to your child's vocalization or label what they might be intending to say.
2. Contingent responses plus vocal elicitation strategies condition: As in the contingent responses condition, the interventionist systematically responds to more complex child vocalizations with more complex responses. The difference is that the interventionist also uses vocal toys (e.g., microphones that distort and/or amplify voices) within engaging turn-taking activities/routines (e.g., blowing bubbles, balloons, and vehicles with sound effects) to further encourage your child to make sounds.
3. Non-contingent control condition: Instead of responding to the sounds that the child is making during the session, the interventionist responds based on a recording they are listening to through an earpiece (e.g., AirPods). Consequently, the interventionist is providing the same types of responses as the other conditions, but they are not timed to what the child is doing at that moment.

Each session will take about 20 minutes. We will video record the session so that authorized study team members can (a) count how many vocalizations your child makes, (b) measure how complex your child's vocalizations are, (c) make sure the interventionist does each step of the procedures correctly, and (d) evaluate the feasibility and social validity of the study procedures. All information about your child, including videos will be kept in locked cabinets or on password protected computers and/or external hard drives indefinitely, unless otherwise specified by the consenting caregiver. To participate in the study, video recordings must be kept at least until data collection is completed. Only authorized study team members will have access to the recordings.

We expect to work with your child for approximately 6 to 8 weeks. The specific amount of time depends on your child's pattern of performance and number of sessions completed per week.

If your child participates in the vocalization intervention, we will ask you to complete a brief survey about the study goals (i.e., importance of communication and language for your child). This survey takes about 5 minutes.

What are the costs?
There is no cost to you for taking part in this study.

What good things might come from this study?
a) The benefits to science and humankind that might result from this study: Participation may help us learn the best ways to teach children with autism to talk.
b) The benefits you might get from being in this study: You will receive a letter with the results of your child's assessment(s). You may share these results with your child's educators, speech-language pathologist, and other professionals. Your child may benefit from participation by using more vocalizations and/or words. They will also receive monetary compensation for their time completing the study

Are there any risks or discomforts for this study? Can anything bad happen to you?
The only anticipated risks are fatigue / boredom and breach of confidentiality. These risks of fatigue / boredom do not exceed those experienced within an educational setting. We use motivating tasks and a variety of activities tailored to your child to minimize these risks. If your child becomes upset during parts of the intervention, we will take breaks and re-introduce the activities once your child appears ready (e.g., sitting calmly). All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed.

What are the unforeseeable risks?
There may be risks that we do not know about.

How can you find out the results of the study?
You will receive a letter with the results of your child's assessment(s). The research team is also available to discuss your child's performance across the different intervention conditions after the study is complete. That discussion may help you learn more about what helps your child learn. Aggregated data across participants will be shared through academic means such as professional conferences and research articles.

What compensation will you receive for participating in the study?
Children who complete the study will receive $100.00 (as an electronic or physical gift card or check) at the conclusion of the study. These participants must complete the eligibility evaluation and vocalization intervention sessions.

Participants who complete the eligibility evaluation and are eligible to participate but withdraw at any point prior to completing the vocalization intervention sessions will receive $25.00 at the conclusion of the study. Potential participants who complete the eligibility evaluation will receive $25.00 if they are not eligible to participate in the study after completing the necessary assessments.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Are there any reasons the researchers may remove you from the study?
If a child indicates they do not want to participate (though verbal and/or nonverbal means), the interventionist offers a break and then invites the participant to engage in the activity again. If the child continues to verbally and/or nonverbally indicate that they do not want to participate (e.g., running away or crying) after three consecutive attempts to re-engage, the session is discontinued. If a child declines to participate during three consecutive sessions, we will discontinue intervention with that participant and discuss that discontinuation with their caregivers.

What happens if you choose to stop being in the study?
You may withdraw your consent to participate in this study at any time. You also have the right to cancel your permission to use and disclose further information collected about your child, in writing, at any time, by sending your written request to: Jena McDaniel at jena.mcdaniel@vumc.org or 1215 21st Avenue South, MCE South Tower Suite 8310, Nashville, TN 37232. If you cancel permission to use your child's information, the researchers will stop collecting additional information about your child. However, the research team may use and disclose information that was gathered before they received your cancellation, as described above.

Who can you talk to about this study?
If you should have any questions about this research study or possibly injury, please feel free to contact Jena McDaniel at jena.mcdaniel@vumc.org, 615-936-5114, or 1215 21st Avenue South, MCE South Tower Suite 8310, Nashville, TN 37232.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

How will your confidentiality and privacy be maintained?
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We may share some information about you for others to use for research, but to protect your privacy we will not share information that could identify you, like your name. The principal investigator or trained research team member will de-identify the data by using a study ID number in place of your child's name. This study ID number will be used through all research activities. Your name and your child's name will not be associated in any publication or presentation with the information collected about you or with the research findings from this study. Instead, we will use a study ID number or not include a name rather than your name or your child's name. Your identifiable information will not be shared unless required by law or you give written permission. Any forms or correspondences that contain identifiable material will be shredded with a secure shredder. Your contact information will be retained for up to 5 years past the end of the study.

The information collected about your child will be used by Jena McDaniel (Principal Investigator) and authorized members of the research team. Permission granted on this date to use and disclose your child's information remains in effect indefinitely. By signing this form, you give permission for the use and disclosure of your child's non-identifiable information for purposes of this study at any time in the future.

All data collected will be stored in electronic files or in locked file cabinets. All assessment data and medical/developmental history data will be de-identified. Electronic files will be stored securely in compliant locations, such as a database server or cloud storage. Electronic files may also be stored on hard drives and stored in a locked location to ensure that study data are not lost. Hard copies of study data documents will be stored in a locked location. Response forms may be scanned and stored in computer files. Only authorized research team members will have access to the locked locations. Jena McDaniel may take a copy of the study records on an external hard drive if she leaves Vanderbilt University Medical Center.

You have the option of providing consent for your child's video and/or audio recordings to be placed in a repository for use in the future studies (option 3). Those studies would be conducted in accordance with the Human Research Protections Program guidelines. Topics of future studies include but are not limited to more detailed analyses of your child's responses or the intervention components. These studies may be conducted in collaboration with researchers at other institutions.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study, future research, or insurance purposes. Disclosures that you make yourself are also not protected.

Principal Investigator: Jena McDaniel, PhD, CCC-SLP **Revision Date: 2025-03-04**
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Institution/Hospital: Vanderbilt University Medical Center

If you would like your child to participate in the study, fill in the information and sign below. Return this consent form to us by mail (Jena McDaniel, 1215 21st Avenue South, MCE South Tower Suite 8310, Nashville, TN 37232) in the envelope provided. Please keep the second copy of this consent form.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Please mark yes or no for each of the options below. Selecting "Yes" for the first two bolded options is required for study participation. Please read each option carefully and contact Jena McDaniel with any questions.

___ Yes ___ No **1. I freely and voluntarily choose to have my child participate and to complete the parent report assessments.**

___ Yes ___ No **2. I agree for the research team to use my child's video and/or audio recordings for the specific purposes of this study until data collection is complete.**

___ Yes ___ No 3. I agree for the research team to include my child's video and/or audio recordings in a repository for future studies. The research team must receive appropriate approval for future uses in accordance with Human Research Protections Program guidelines.

___ Yes ___ No 4. I agree for the research team to use my child's video and/or audio recordings in teaching or professional development workshops.

___ Yes ___ No 5. I agree to be contacted in the future about studies my child may be eligible to participate in.

Child's name: _____ Date of birth: _____

Complete address: _____

Phone: _____ Email: _____ Today's date: _____

Parent/Guardian signature: _____

Parent/Guardian name: _____ Relationship to child: _____

Consent obtained by:

_____ _____ _____
Date Signature Printed Name and Title