VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Meganne Muir **Revision Date: 3/19/2025**
Study Title: Project PAIR: Parent-enhanced Articulation Intervention with Recast
Institution/Hospital: Vanderbilt University

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 articulation for children who are deaf and hard of hearing.
- Children who are deaf and hard of hearing aged 4 to 9 years old who use spoken English are invited to participate. Children who also use sign language or Total Communication may participate.
- Participation of you and your child in this project is completely voluntary. You can choose not to participate in this study. You and your child may stop participating at any time.
- Your participation as a caregiver will involve two 30–60-minute training sessions to learn a new teaching strategy that will be implemented at home. You will continue to use this strategy during your interactions with your child throughout the study.
- Your child's participation will take approximately 30–45 minutes per speech therapy session, three times per week, for up to approximately four months. The specific duration varies depending on the child's pattern of performance.
- You will be asked to complete a demographics and background information form and a 15- to 20-minute interview about your child's language experience (which is described in more detail below).
- The only anticipated risks are fatigue and boredom. These risks do not exceed those experienced within an educational setting.
- Your child can earn up to $200 for completing the study.
- Participation may also help us learn the best ways to teach children who are deaf and hard of hearing to develop their articulation skills.

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 is deaf or hard of hearing and aged 4- to 9-years-old. We know that children who are deaf and hard of hearing often have difficulty accurately producing certain speech sounds when they talk. Therefore, they can be harder to understand than expected for their age. We want to learn more about how to help children who are deaf and hard of hearing learn to talk clearly.

Do you have to be in this research and can you stop if you want to?
You and your child 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 to be in this study.

What will you do and how long will it take?

Speech-Language Evaluation

If you choose for your child to participate, we will first complete a speech-language evaluation (~2 to 2.5 hours) to determine whether your child is eligible to participate. The evaluation can be completed in two sessions if your child gets 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. Additionally, if you agree, we will request your child's Individualized Education Plan (IEP) and/or last full evaluation report to learn about the services your child is receiving. We will also ask you to engage in a conversation (approximately 15 to 20 minutes) about your child's language experience to complete the Language Access Profile Tool.

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, if desired, regardless of eligibility.

Parent Training and Recast Intervention

This study is interested in understanding how a combination of home-based parent strategies and speech therapy from an interventionist can improve a child's articulation. You or another primary caregiver will participate in two 30-60-minute training sessions to learn a new teaching strategy for your child. The strategy is called recast, and it involves repeating your child's sentence in a corrected form, using proper grammar and articulation (e.g., changing "ah lie da" to "I like dogs"). During the training sessions, the interventionist will teach you how to use this strategy and provide opportunities for you to practice it with your child. After you complete the training, you will use this strategy at home when interacting with your child throughout the day. You will be sent three texts per week reminding you to use the recast strategy and asking you to rate your use for a particular day. You will also be asked to send an audio recording of you and your child using recast up to once per week. Your use of this strategy should continue throughout the study.

Speech Therapy Intervention

Your child will engage in 1-3 sessions per week with an interventionist. Each session will take about 30-45 minutes. The interventionist will encourage your child to say a list of target words based on the sounds that he/she has difficulty producing. Sometimes your child will be given feedback on how to improve these productions, such as where to place their tongue. Short games may be played during the session to increase focus and engagement.

Location and Procedures

Parent training sessions and/or child intervention sessions may take place at a variety of locations, including your child's school or home, a community location (e.g., library, childcare setting), our lab, or virtually via a video conferencing platform. Completing sessions at your home is optional. You may choose another location. We will video record the sessions so that authorized study team members can track your child's articulation progress and make sure the interventionist does each step of the procedures correctly. All information about your child, including videos, will be stored indefinitely on the HIPAA-compliant, encrypted server, cloud storage, and/or hard drive, unless otherwise specified by you. To participate in the study, video recordings must be collected and kept at least until data collection is completed. You may choose at the end of this document whether you give permission for the video recordings to be retained after data collection. Only authorized study team members (e.g., principal investigator and research assistants) will have access to the recordings.
Your child will complete some of the assessments from the eligibility speech-language evaluation after completing the speech intervention to assess change. We expect to work with your child for approximately three months. The specific amount of time depends on your child's pattern of performance.

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 who are deaf and hard of hearing develop their articulation skills.

b) The benefits you might get from being in this study:
You will receive a letter with the results of your child's assessments, if you mark "Yes" for option 6 at the bottom of this form. You may share the results from the assessment with your child's educators, speech-language pathologist, and other professionals. During the speech therapy intervention phase, your child will receive targeted speech therapy with an intervention plan built for their specific speech sound errors. You will receive training in a strategy that has been documented to improve speech and language development within the home.

Are there any risks or discomforts for this study? Can anything bad happen to you?
The only anticipated risks are fatigue and boredom. These risks 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).

How can you find out the results of the study?
You may choose to receive a letter with the results of your child's assessments. The research team is also available to discuss your child's performance across the parent recast phase compared to the parent recast and speech therapy phase after the study is complete. That discussion may help you learn more about how your child best improves their speech skills. 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?
Participants who complete the study will receive $200.00 (as an electronic gift card or check) at the conclusion of the study. These participants must complete the speech-language assessments, baseline, and intervention sessions.

Participants who participate in intervention sessions but do not complete the study due to lack of progress (defined as no progress across 6 sessions), will receive $200.00 at the conclusion of the study. Participants who complete the speech language evaluation, are eligible to participate, but withdraw at any point prior to completing the maintenance sessions will receive $25.00 at the conclusion of the study. Potential participants who complete assessments required for inclusion/exclusion criteria will receive $25.00 if they are not eligible to participate in the study after completing the necessary assessments.

We may ask you for your Social Security number and address before you are compensated for taking part in this study.

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 your child indicates he or she does not want to participate (through verbal and/or nonverbal means), the principal investigator or research assistant 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 he or she does 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 his or her parents.

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 Meganne Muir at meganne.muir@vanderbilt.edu or the Faculty Advisor, Jena McDaniel at jena.mcdaniel@vumc.org, 615-936-5114.

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 Meganne Muir (Principal Investigator), Jena McDaniel (Faculty Advisor) 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 HIPAA-compliant locations, such as a HIPAA-compliant 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 4). 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 or future research. Disclosures that you make yourself are also not protected.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

If you want 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.

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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. Please read each option carefully and contact Jena McDaniel or Meganne Muir with any questions.

___ Yes ___ No **1. I freely and voluntarily choose to have my child participate.**

___ Yes ___ No **2. I freely and voluntarily choose to participate.**

___ Yes ___ No **3. I agree for the research team to use video and/or audio recordings of me and my child for the specific purposes of this study until data collection is complete.**

___ Yes ___ No 4. I agree for the research team to include video and/or audio recordings of me and my child 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 5. I agree for the research team to use video and/or audio recordings of me and my child in teaching or professional development workshops.

___ Yes ___ No 6. I would like a copy of my child's speech and language assessment results.

___ Yes ___ No 7. I agree to be contacted in the future about studies my child may be eligible to participate in.

Parent/Guardian signature: _____ Today's date: _____

Parent/Guardian name: _____ Relationship to child: _____

Child's name: _____ Date of birth: _____

Complete address: _____

Phone: _____ Email: _____

The researcher will complete this section.
Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title