Informed Consent Form

Study Title: Retrieval Practice for Word Learning for Deaf and Hard of Hearing Children

NCT Number: NCT05512000

Document date: Approved by IRB on 02/27/2025

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Jena McDaniel, PhD, CCC-SLP **Revision Date: 02/07/2025**
Study Title: Increasing Word Learning Efficiency in Children who are Deaf and Hard of Hearing through Retrieval Practice
Institution/Hospital: Vanderbilt University Medical Center

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

- This project is studying how to improve spoken word learning for children who are deaf and hard of hearing.
- Children who are deaf and hard of hearing aged 5 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 and your child may stop participating at any time.
- Your child's participation will take approximately 30-45 minutes per session, 3 times per week, for up to approximately 3 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 language skills.
- You can choose not to participate in this study.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Your child is being asked to take part in this research study because your child is deaf or hard of hearing and aged 5 to 9 years old. We know that children who are deaf and hard of hearing often have difficulty learning new words. We want to learn more about how to help children who are deaf and hard of hearing learn words faster.

Your child does not have to be in this research study. You may choose not to have your child in this study and get other treatments without changing your healthcare, services, or other rights. Your child can stop being in this study at any time. 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.

Procedures to be followed and approximate duration of the study:

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. The form takes about 5-10 minutes.

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.

Vocabulary Intervention

The intervention focuses on teaching your child spoken words. Your child will participate in vocabulary learning activities with the interventionist. The interventionist will introduce the target words, explain their meanings, and engage your child in activities that focus on the target words (e.g., coloring pictures). Sometimes your child will be given feedback on their performance. Sometimes they will not. The words will be presented in different orders. We are interested in whether the feedback and certain ways of ordering the words help children learn the vocabulary words.

Your child will engage in three sessions per week. Each session will take about 30 to 45 minutes. We will video record the sessions so that authorized study team members can count how many words your child has learned and make sure the interventionist does each step of the procedures correctly. All information about your child, including videos, will be kept 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 vocabulary intervention to assess change. We expect to work with your child for approximately two to three months. The specific amount of time depends on your child's pattern of performance.

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.

Expected costs:

There is no cost to you for taking part in this study.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

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).

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study. Participation may help us learn the best ways to teach children who are deaf and hard of hearing to develop their language skills.

b) The benefits you might get from being in this study. You will also receive a letter with the results of your child's assessment(s), if you mark "Yes" for option 6 on page 6. You may share the results from the

assessment with your child's educators, speech-language pathologist, and other professionals. Your child will also receive monetary compensation for his or her time completing the study.

Study results:
You will receive a letter with the results of your child's assessment(s), if you mark "Yes" for option 6 on page 6. The research team is also available to discuss your child's performance across the different teaching conditions after the study is complete. That discussion may help you learn more about what helps your child learn words. Aggregated data across participants will be shared through academic means such as professional conferences and research articles.

Compensation for participation:
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, intervention, and maintenance sessions.

Participants who participate in intervention sessions, but do not complete the study due to lack of progress, defined as plateauing (no progress across 6 sessions) twice, 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.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

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.

Circumstances under which the Principal Investigator may withdraw you from study participation:
If a participant indicates he or she does not want to participate (though 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 caregivers.

What happens if you choose to withdraw from study participation?
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.

Contact Information. 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.

Confidentiality:
All efforts, within reason, will be made to keep your child's information in their research record confidential but total confidentiality cannot be guaranteed. 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 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.

Privacy:

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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.

Principal Investigator: Jena McDaniel, PhD, CCC-SLP **Revision Date: 02/07/2025**
Study Title: Increasing Word Learning Efficiency in Children who are Deaf and Hard of Hearing through Retrieval Practice
Institution/Hospital: Vanderbilt University Medical Center

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.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document. 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 are 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 access my child's medical records, including audiological records, for purposes of this study.

___ Yes ___ No 4. 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 5. I agree for the research team to use my child's video and/or audio recordings 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.

Child's name: _____ Date of birth: _____

Complete address: _____

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

Parent/Guardian signature: _____

Parent/Guardian name: _____ Relationship to child: _____

The researcher will complete this section.

Consent obtained by:

Name: _____ Title: _____

Signature: _____ Date: _____

Date of IRB Approval: 02/27/2025