

## COVER LETTER

Informed Consent (Parental Permission Form)

Title of the Project: Determining the Optimal Treatment Intensity for Children with Language Impairment

NCT #: NCT04501536

Date: April 21, 2022



Title of the Project: Determining the Optimal Treatment Intensity for Children with Language Impairment

Principal Investigator: Mary Beth Schmitt, PhD, CCC-SLP; University of Texas at Austin

Co-Investigator: Laura Justice, PhD, CCC-SLP; The Ohio State University

Independent Investigator: Sherine Tambyraja, PhD

Study Sponsor: National Institutes of Health

### **Parental Permission for Child Participation in Research**

#### **Invitation to be Part of a Research Study**

We would like to invite your child to be part of a research study. This permission form will help you in choosing whether or not to allow your child to participate in the study. Feel free to ask if anything is not clear in this consent document.

#### **What is the study about and why are we doing it?**

The purpose of the study is to determine the amount of speech-language intervention children need to make improvements. We hope to identify the appropriate amount of intervention needed as well as the point at which adding more intervention is no longer beneficial.

#### **What will happen if your child takes part in this study?**

All parts of the study will be conducted online. If you do not have access to the internet or technology, your family may qualify to receive technology from the lab that can be used throughout the duration of the study.

If you agree to allow your child to take part in this study, your child will be asked to:

- Complete a 2-hour testing session to establish baseline skills. This will include a questionnaire to be completed by you helping us understand the child's home environment.
- Your child will be randomly assigned (like a flip of a coin) to attend either one time a week for 10 weeks (2 hours a session) or 4 times a week for 10 weeks (30 min per session). This will be a 1-on-1 session with a speech-language pathology intern.
- During these sessions, the child will engage in story book reading activities. The child does not need to know how to read to participate.
- After the 10 weeks of book reading activities, the child will complete another 2-hour testing session.
- 6-months later, the research team will ask your child to come back in for a follow-up testing session (2 hours) to assess his/her retention of learned skills.
- The testing for this study will in no way impact your child's eligibility for services in the schools and will not be communicated with school personnel.

#### **How long will your child be in this study and how many children will be in the study?**

Participation in this study will last for approximately 10 weeks with one 2 hour session before the book reading intervention, one 2 hour session after the book reading intervention and a 6-month follow up. A total of 180 children will be enrolled in the study.

#### **What risks and discomforts might your child experience from being in this study?**

There are some risks your child might experience from being in this study. They are fatigue or boredom during the book-reading activities. To minimize this effect, clinicians will have engaging, age-appropriate books and activities for the children. Children will have breaks as needed and can bring a

snack or water to increase comfort. There is a minimal risk of breach of confidentiality, although many steps will be taken to safeguard this from happening.

**How could your child benefit from this study?**

Your child might benefit from being in this study because he/she will receive additional intervention from a trained, speech-language pathology intern.

**What will happen to the samples and/or data we collect from your child?**

As part of this study we will collect assessment data from your child at the beginning, end, and 6-months post study. We will also request educational data from your child's school based speech-language pathologist. This will include copies of your child's Individualized Educational Plan (IEP) and language therapy records. Identifiable records will not be reported or disclosed to any other party for any reason.

These data will be de-identified such that your child will receive a unique ID. This ID will be included on all forms and data and your child's name will be removed to protect their confidentiality. All data will be stored in the Pls' labs behind 2 locked doors that are only accessible to team members on this project. All digital data will be de-identified and stored on password-protected.

Your child's sessions may be video-taped during the study. These videotapes would be used for research purposes only, to ensure that all children are receiving the intervention as designed. Once the videos have been coded and assessed by members of the research team, all video data will be erased.

**How will we protect your child's information?**

We will protect your child's information by assigning a unique ID number to your child. All data regarding your child will be de-identified (his/her name and any identifiable data will be removed or whited-out and the unique ID number will be added). All data will be stored in the Pls' labs behind 2 locked doors that are only accessible to team members on this project. All digital data will be de-identified and stored on password-protected. Your child's name and any other information that can directly identify your child will be stored separately from the data collected as part of the project.

Information about you may be given to the following organizations:

- The study sponsor and/or representative of the sponsor
- Representatives of UT Austin and the UT Austin Institutional Review Board
- Other collaborating organizations: The Ohio State University

To help us protect your child's privacy we will apply for a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify your child, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the certificate to resist any demands for information that would identify your child, except as explained below. The certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you, your child, or a member of your family from voluntarily releasing information about your child or your child's involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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

**What will happen to the information we collect about your child after the study is over?**

We will keep your child's research data to use for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers will not include information that can directly identify your child.

**How will we compensate your child for being part of the study?**

You will receive \$100 in cash for participating. Payments will occur at each of three testing periods:  
\$25 after pretesting  
\$50 after the 10 week intervention/post testing.  
\$25 after the 6-month follow up testing session.

You are not waiving any of your or your child's legal rights by allowing your child to participate in this study. You are responsible for any income tax requirements for amounts received.

**What other choices does my child have if you do not take part in this study?**

There may be other ways of treating your child's condition if you do not wish to allow your child to be in this research. Check with your health care provider to discuss other options.

**Your Child's Participation in this Study is Voluntary**

It is up to you and your child to decide to be in this research study. Participating in this study is voluntary. The decision to participate will not affect your or your child's relationship with The University of Texas at Austin or your child's school. You and your child will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to allow your child to be part of this study now, you may change your mind and stop at any time. Your child does not have to answer any questions they do not want to answer. If you decide to withdraw your child from the study before it is completed, the data collected to date will remain de-identified as a part of the larger study.

**Contact Information for the Study Team and Questions about the Research**

If you have any questions about this research, you may contact:

Dr. Mary Beth Schmitt

The Children's Language, Literacy & Learning Lab

Phone: 512-232-5101; Email: [cl3@austin.utexas.edu](mailto:cl3@austin.utexas.edu)

**Contact Information for Questions about Your Rights as a Research Participant**

If you have questions about your rights or your child's rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board

Phone: 512-232-1543

Email: [irb@austin.utexas.edu](mailto:irb@austin.utexas.edu)

Please reference study number 2019-09-0029.

**Your Permission**

By signing this document, you are agreeing to allow your child to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree to allow my child take part in this study.*

\_\_\_\_\_ I agree for my child to be [audio and/or video] recorded.

\_\_\_\_\_ I do not agree for my child to be [audio and/or video] recorded.

\_\_\_\_\_  
Printed Subject Name

\_\_\_\_\_  
Signature of Parent or Legal Guardian

\_\_\_\_\_  
Date

## Parental Permission for Release of Educational Records

### What is this document?

By signing this document, you are agreeing to allow your child's school to release educational records to our research team. This will include copies of your child's Individualized Educational Plan (IEP) and language therapy records. This information will help us understand how school therapy and this current intervention study work together on your child's progress. Identifiable information will not be reported or disclosed to any other party for any reason.

### Information to be released/exchanged:

- All *current and previous* therapy evaluations/assessments and re-evaluations/re-assessments
- All *current and previous* therapy progress notes
- All *current and previous* therapy discharge summaries
- All *current and previous* documents related to language therapy
- All *current and previous* Individualized Education Plans (IEPs)
- Questionnaire related to child's language abilities and therapy environment

### Information will be shared between:

#### FROM:

School Name: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip Code: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

#### TO:

Professor Mary Beth Schmitt, Ph.D., CCC-SLP  
Department of Communication Sciences and  
Disorders  
The University of Texas at Austin  
2504A Whitis Ave. (A1100)  
Austin, TX 78712-0114

Laura Justice, PH. D.  
Crane Center for Early Childhood Research and  
Policy  
The Ohio State University  
175 E. 7th Avenue  
Columbus, OH 43210-1172

### Your Permission

\_\_\_\_\_ I authorize the information above to be released/exchanged between my child's school and UT researchers.

\_\_\_\_\_ I approve communication between my child's school and UT researchers to facilitate release/exchange of the information above.

\_\_\_\_\_  
Student Name

\_\_\_\_\_  
Student Date of Birth

\_\_\_\_\_  
Signature of Parent or Legal Guardian

\_\_\_\_\_  
Date