CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: Improving STEM Outcomes for Young Children with Language Learning Disabilities by Intervening at the Intersection of Language and Scientific Thought via Teletherapy

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KEY INFORMATION

Important aspects of the study you should know about first:

- **Purpose:** The purpose of the study is to study whether treating vocabulary or grammar during science instruction leads to better science learning.
- **Procedures**: If you choose to have your child participate, you will be asked to complete some questionnaires about your child, your child will complete tests of language and science knowledge to see if they are eligible for the study, your child will receive language treatment and science instruction via teletherapy, and your child will complete posttest measures to determine what they learned.
- **Duration:** This will take about 1-6 tele-assessment visits to determine eligibility and complete pre-test measures, 12 tele-therapy sessions spread over 6-8 weeks, and up to 3 post test tele-assessment visits. Each visit lasts about an hour.
- **Risks**: The main risk or discomfort from this research are loss of confidentiality, anxiety about your child's performance, and boredom.
- **Benefits:** The main benefit to you from this research is the potential to benefit from language therapy and/or science instruction.
- **Alternatives:** You may access language therapy through your public school for free if your child is eligible for special education services in your district.
- **Costs and Compensation:** If you decide to participate there will be no additional cost to you and you could be compensated up to $125.
- **Participation:** Taking part or not in this research study is your decision. You can decide to participate and then change your mind at any point

Please carefully read the entire document. You can ask any questions you may have before deciding If you want to participate.

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you want to participate.

PURPOSE OF THE STUDY

The purpose of this study is to learn more about which treatment targets lead to better academic outcomes for children with language disorders. There is frequently not enough time to provide treatment for all areas of concern and this will help Speech language pathologists know which areas of support lead to the largest functional outcomes in the area of academic (science) learning.

WHO IS BEING ASKED TO PARTICIPATE?

Your child will be one of approximately 500 children screened for eligibility. We anticipate that around 66 children will be eligible for participation and receive treatment in this study.

Your child is being asked to participate because they speak English as their primary language, are between the ages of 4 and 7, are not yet in first grade, and have a suspected or diagnosed language disorder. Children with additional concerns like autism, intellectual disability, hearing loss, or a genetic syndrome, or who are not yet using simple 3-4 word sentences consistently are not eligible for this study. During the screening phase of the study we will confirm the presence of a language disorder and complete assessments to determine if your child is likely to be able to benefit from the instruction provided. You must have reliable access to a computer (mac or PC) and broadband internet to participate in this study.

PROCEDURES: WHAT WILL YOU BE ASKED TO DO?

As part of this study you will be asked to participate in tele-assessment and tele-therapy procedures. All study activities will take place via Zoom. We may audio or video record these sessions via Zoom and store them on secure university servers for the purpose of documenting our procedures and for the purpose of scoring/documenting your child and the clincians' performance later (e.g., treatment fidelity, child productions during treatment or during probes, scoring reliability).

- Your participation in this study will take up to 28 hours. You will be asked to participate in 1 visit to complete consent documents, parent intake forms, and confirm your technical resources (computer, broadband). If needed we will attempt a second tech-check to resolve any problems that were initially identified. Then your child will participate in up to 3 screening visits to determine eligibility. If they are eligible to participate in the treatment, we will complete up to 3 pretest visits. They will be assigned to a tele-therapy group with up to 3 additional children and participate in 12 group tele-therapy visits of 40-60 min each over 6-8 weeks. During the treatment period, we will also ask you to have your child watch short (10 min) video book reading to expose them to the language and science content on days when the treatment is not occurring. Finally, we will ask your child to participate in up to 3 posttest visits. Each visit will typically last 1 hour.
- Visit 1 – Consent, Intake Questionnaires, Technical Check (20-40 min visits) We will meet with you over Zoom to complete informed consent documents (this document), answer any questions you have about the protocol, and go over initial parent questionnaires that you will complete online. Ideally, we will do this using the computer and in the location that we will do future tele-assessment and teletherapy visits with

your child so that we can confirm that Zoom has properly installed on the device and connectivity is adequate to support participation. If an ethernet cable or a headset is required for full participation, we will mail those to you and schedule a second tech check visit to confirm availability. Your child is not required to attend these visits.

- Visits 2-4 Eligibility Screening (60 min visits) We will assess your child's speech, language, cognitive, and hearing skills to determine if they are eligible to participate in the study. To be eligible, your child must meet a research definition of having a language impairment as their primary area of concern. They also must have enough difficulty with the particular treatment targets we are teaching so that they can benefit from therapy. At the end of eligibility testing, we will share standardized test results with you if you would like and will let you know if your child can continue in the study or not. We will begin discussions about scheduling group teletherapy visits in coordination with other qualifying families.
- Visit 5-7 Pre testing (60 min visits) We will test your child's science and vocabulary skills. These are not things that will keep your child from participating the study, but they allow us to better document skills before therapy begins so we can determine growth over time.
- Visits 8-21 Tele-therapy visits (40-60 min visits) Your child will be assigned to one of three treatment conditions (Grammar + Science, Vocabulary + Science, Science Only). For children who qualify, there will be one optional visit for the children paired in groups to get to know each other and engage in a provided craft activity. They will receive treatment twice a week from a speech language pathologist licensed in the state of Delaware and learn about the physical properties of air, light, and sound with a group of up to 4 children who also have speech/language concerns. We will mail you some materials for use during these visits (e.g., a tuning fork, a small fan, bubbles, a small flashlight) to support science learning. We will also ask that you have your child watch a short video (<10 min) of a book read aloud to reinforce science and language content on the days when they do not have treatment. The book will be available through a dedicated platform accessible via your web browser. The science activities are based on a published science curriculum used for first grade children (FOSS-NGSS) and the language intervention techniques are known evidence-based practices that have documented efficacy.
- Visit 22-24 Post test visits (60 min visits). Your child will retake some of the assessments from eligibility screening and pretesting to document change based on participating in treatment.

You may choose not to participate in this study and follow traditional treatment programs through your school, preschool, or private practice. If you are currently receiving speech/language treatment or enrolled in academic programs we encourage you to continue these during the course of the study.

WHAT ARE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks of participating in this research study include anxiety, boredom and fatigue, and loss of confidentiality. You may feel anxiety about your child's performance on the tasks we ask them to do. We will attempt to explain the tests that we give and the activities we present so that you can understand them. Please ask us any questions you have. Your child may experience boredom or fatigue during the tasks. We try to make things kid friendly and we will work with you to engage your child at their best time of day and using techniques that work for them. You share

some confidential information with us and, while we protect your information using alphanumeric codes and secure servers, there is always the risk of loss of confidentiality.

WHAT ARE POTENTIAL BENEFITS FROM THE STUDY?

You and your child may benefit from participating in this research study. Your child may learn science content that will support their academic success. They may also improve in their vocabulary or grammar skills. Even if they are assigned to the Science only condition, participating in regular language-rich activities may benefit their language. The degree of benefit cannot be guaranteed for any individual child, but all strategies and curricula we use are evidence based and have the potential to yield benefits.

This study may also yield knowledge that will benefit society by helping us to better understand how to integrate curricular content and language intervention for children with language impairment.

NEW FINDINGS THAT COULD AFFECT YOUR PARTICIPATION

During the course of this study, we may learn new important information. This may include information that could cause you to change your mind about participating in the study. If any new important information becomes available while you are a participant we will let you know.

CONFIDENTIALITY: WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

We will keep your child's participation in this research study confidential to the extent possible. We cannot guarantee that group members in the teletherapy sessions will maintain confidentiality also. We will minimize the information about you and your child that we share with them, but they may know your identity. It is not possible to fully anonymize audio and video records. However, we will store personal information separate from your files and we will identify you in how we store the records via an alphanumeric code rather than your name.

In addition, it is possible that other people such as those indicated below may become aware of your child's participation in this study and may inspect and copy records pertaining to this research. Under Delaware law, researchers are required to report to the appropriate authorities any information concerning child abuse or neglect. The researchers may also report threats of harm to self or to others. Some of those records could contain information that personally identifies your child.

- Federal government regulatory agencies
- Auditing departments of the University of Delaware
- The University of Delaware Institutional Review Board (a committee that reviews and approves research studies)

To help protect your child's confidentiality, we will use an alphanumeric code to track your child's participation. Paper records will be stored in a locked lab in room 109 on the STAR campus and all electronic records, including audio- and video-recordings, will be stored on cloud-based computing servers under password protection.

We intend to store and share video and audio data and the results of the experimental tasks with researchers at the University of Iowa and Boystown National Research Hospital. This data will also be stored on Boystown National Research Hospitals computing servers.

If we write a report or article about this study, we will do so in such a way that your child cannot be directly identified. 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. At most, the Web site will include a summary of the results. You can search this Web site at any time.

COSTS AND COMPENSATION

There are no costs associated with participating in the study.

You will be paid $5 for completing the initial screening visits, regardless of whether you qualify for the remainder of the study or not. You will be paid $20 for completing the pretest visits. During treatment, you will be paid $0.50 for each book you read with your child, up to $15.00 total. You will be paid $100 for completing the post test visits.. We will compensate you at the completion of screening + pretest visits and at the end of post testing with e-gift cards. We will only pay you for the portion of the study that you have completed. Thus you may receive between $5 and $140 depending on how much of the study you complete.

In addition, if you need it to participate, we will provide you with a head set, headphone splitter, and an ethernet cord that you do not need to return. Likewise, any materials we provide for completing science activities do not need to be returned

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide later not to participate, or if you decide to stop taking part in the research, there will be no penalty or loss of benefits to which you are otherwise entitled.
Your decision to stop participation, or not to participate, will not influence current or future relationships with the University of Delaware or Boystown National Research Hospital.

The investigators reserve the right to remove you from the study without your consent if you miss more than 3 pretest or screening visits or more than 5 treatment visits for any reason or if we have reason to believe that your child is not assenting to the treatment itself. Although children participating in this study are too young to formally

consent, we do monitor "assent" – your child's willingness to participate in the study. Children do not have to participate in research if they do not give assent/are unwilling to participate in the study. We know that young children may not want to do each activity we offer over the course of the study, and we are prepared to offer other options for your child if this occurs. If your child is repeatedly withdrawing assent, we will attempt to determine the reason and make modifications to support your child. If your child continues to be unwilling to participate with all the support we can offer, we will consult with you regarding our concerns and we may end your child's participation in the treatment phase of the study. Although we will consult with you, ultimately, we are required to honor your child's assent. We will still contact you to attempt to complete the post-testing phase of the study if possible.

INSTITUTIONAL REVIEW BOARD

This research study has been reviewed and approved by the University of Delaware Institutional Review Board (UD IRB), which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. If you have any questions or concerns about your rights as a research participant, you may contact the UD IRB at hsrb-research@udel.edu or (302) 831-2137.

CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues related to this research study you may contact the Principal Investigator, Amanda Owen Van Horne at (302) 831-3982 or ajovh@udel.edu.

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY:

I have read and understood the information in this form and I agree to participate in the study. I am 18 years of age or older. I have been given the opportunity to ask any questions I had and those questions have been answered to my satisfaction. I understand that I will be given a copy of this form for my records.

_____	_____	_____
Printed Name of Participant (PRINTED NAME)	Signature of Participant (SIGNATURE)	Date
_____	_____	_____
Person Obtaining Consent (PRINTED NAME)	Person Obtaining Consent (SIGNATURE)	Date

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PLEASE CONTINUE TO THE NEXT TWO PAGES FOR CONSENT FOR OPTIONAL ELEMENTS OF THE STUDY AND USE OF STUDY DATA

<u>OPTIONAL</u> - USE OF DATA COLLECTED FROM YOU IN FUTURE RESEARCH:

As a part of this study, we are obtaining standardized test scores, speech and language recordings, and videos of how your child is learning science. We would like to study your child's data after this study is over. The methods we might want to use to study your child's data may not even exist at this time. Therefore, we ask your permission to store your child's data so that we can study them in the future. It is unlikely that what we learn from these studies will have a direct benefit to you. Your choice about future use of your data will have no impact on your participation in this research study.

_____ I give permission to use the data collected from my child in future studies.

_____ I do not give permission to use the data collected from my child in future studies.

<u>OPTIONAL - TRAINING PRE-SERVICE STUDENTS & OTHER PROFFESSIONALS</u>

We may use data collected from your child for training purposes in later studies, such as by sharing audio or video recordings of your child to teach students, teachers, speech language pathologists, and other researchers how to teach the science lessons. Your choice about future use of your data to help train others will have no impact on your participation in this research study.

_____ I will allow the use of audio and video data collected from my child for training purposes.

_____ I will not allow the use of audio and video data collected from my child for training purposes.

<u>OPTIONAL</u> LAB ADVERTISEMENTS

We frequently need to recruit for our studies and like to feature children in some of our advertisements and on our lab webpage, Facebook page, and other printed or electronic media. Please tell us whether collected videos and still shots from the study can be used for these purposes. We never include the real names of children when using their likeness.

_____ I will allow videos and still shots collected during this study to be used in print/electronic media without additional review.

_____ I will consider allowing videos and still shots collected for this study to be used, but would like to be contacted to review them before they are used.

_____ I do not want any video or images of my child from this study used for these purposes.

<u>OPTIONAL</u> LANGUAGE RESEARCH REGISTRY CONSENT:

The Language Research Registry (LRR) stores participants' contact information *(participant/child's name/parents' names, address, email, phone)* and some demographic (e.g., *birth date, gender, race, self/parent-reported disability, participant/parent education level, language exposure, studies you have participated in*) and standardized test score data collected as a part of this study in a secure, password-protected database.

Researchers in labs affiliated with the Language Research Registry may use this information to contact you about participating in future studies and to conduct approved retrospective studies. Storing your data does not commit you to future participation and we will only add the data you allow us to add. If you wish to remove your or your child's contact information or other data you may do so at any time by contacting the language registry (language-registry@udel.edu).

Your selection will not affect your participation in this study in any way. Please initial your consent for the choices below:

_____ My/my child's **contact information** may be updated/added to the LRR

_____ My/my child's **demographic information** may be updated/added to the LRR

_____ My/my child's **standardized test score information** may be updated/added to the LRR

_____ Do not include/update any of my/my child's information from this study in the LRR

_____ Please remove the following information from the LRR completely

Contact Info Demographic Info Standardized Test Scores

_____ _____

Signature