

KU WORD AND SOUND LEARNING CONSENT STATEMENT
Interactive Book Reading to Accelerate Word Learning by Children with SLI

Your child is invited to participate in a research program on interactive book reading conducted by the Word and Sound Learning Lab at the University of Kansas. The Department of Speech-Language-Hearing at the University of Kansas supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish your child to participate in the present study. You may refuse to sign this form and not allow your child to participate in this study. You should be aware that even if you agree to allow your child to participate, you are free to withdraw at any time. If you do withdraw your child from this study, it will not affect your relationship with this unit, the services it may provide to you, or the University of Kansas.

PURPOSE

The purpose of the research project is to optimize a treatment that has been shown to be effective in promoting word learning for different types of Kindergarten children. However, this treatment has not frequently been used with Kindergarten children with Specific Language Impairment (SLI). Children with SLI have difficulty learning spoken language including vocabulary and sentence grammar without any obvious cause for their difficulty. The treatment is called interactive book reading, meaning that an adult reads a storybook to a child and teaches the new words in the book. The goal of the proposed research is to determine the intensity and the format of interactive book reading that will help children with SLI learn new vocabulary words.

Your child is asked to participate in the task(s) marked below at his or her school, after-school program, or in your home, or at a convenient location near your home (e.g., local library). For school and after-school programs, the classroom teacher or leader will be consulted for scheduling issues. For sessions at or near your home, you will be consulted for scheduling. If sessions occur at your home, you will be asked to provide a quiet room free from distraction.

PROCEDURES

Time Summary Table. Total time commitment for all procedures described below.

Treatment Part 1:				
Preliminary Evaluation	Vocabulary Test Prior to Treatment	Interactive Book Reading Treatment	Vocabulary Test Immediately Following Treatment	Vocabulary Test 2 Weeks Post-Treatment
3-4 hours	1-2 hours	7-12 weeks	1-1.5 hours	1-1.5 hours
3-4 sessions, lasting 30 to 60 minutes	1-2 sessions, lasting 30 to 60 minutes	15-23 sessions, lasting 30 to 45 minutes	1-2 sessions, lasting 30 to 45 minutes	1-2 sessions, lasting 30 to 45 minutes
\$25.00 at end				\$25.00 at end



Treatment Part 2:		
Interactive Book Reading Treatment	Vocabulary Test Immediately Following Treatment	Vocabulary Test 2 Weeks Post-Treatment
7-12 weeks	1-1.5 hours	1-1.5 hours
15-23 sessions, lasting 30 to 45 minutes	1-2 sessions, lasting 30 to 45 minutes	1-2 sessions, lasting 30 to 45 minutes
		\$25.00 at end

Total estimated time frame for completion of the study is: 17-28 weeks depending on whether treatments are scheduled 2 or 3 times a week.

Preliminary Evaluation: Prior to or during the preliminary evaluation, you will be asked to complete a questionnaire related to your child’s development and environment. During the preliminary evaluation, your child will be given several tests commonly used by speech therapists to examine hearing, vocabulary, articulation, overall language expression and comprehension, pre-reading/reading, memory, and nonverbal reasoning. It is anticipated that this testing will require a total of 3 to 4 hours, spread across three to five sessions, with each session lasting 30- to 60-minutes. The following tests may be given during the evaluation session to determine whether your child is eligible to participate in the research project.

- The *hearing test* requires that your child wear headphones and listen to tones.
- The *articulation test* requires your child to name common pictures such as “house” or “cup.”
- The overall language expression and comprehension test requires your child to interpret and follow spoken directions, finish a starter sentence, repeat sentences, use a given word in a sentence about a picture, answer questions about a spoken story, group pictures that are similar and explain how the pictures are similar.
- The vocabulary tests have children finish a starter sentence, answer questions about pictures, and describe a pictured event. .
- The *pre-reading/reading test* requires your child to say a word and then say it again without a part of the word (e.g., cupcake without cup = cake), say parts of a word and then combine them to say the full word (e.g., cup – cake = cupcake), match words that sound similar (e.g., cake-rake), and read letters and words.
- The *memory test* requires your child to repeat nonwords of various lengths and lists of numbers of various lengths.
- The *nonverbal reasoning test* requires your child to look at a set of pictures and select the one that doesn’t belong or identify something that is missing.
- The *supplemental language test* may be given to some children. This test requires your child to answer questions with or without pictures, describe, tell stories or ask questions about



pictures, select pictures that match spoken sentences, finish a starter sentence (e.g., fill-in-the-blank), remember new words, and repeat sentences.

The articulation, nonword repetition, pre-reading/reading, and language expression tests and sentence repetition tests will be audio recorded and used to transcribe your child's production of each word. All tests will be video recorded and used to score your child's performance. Audio and video recordings may be used to train research assistants and undergraduate/graduate students in research or speech-language pathology procedures. If these recordings are used for teaching purposes, your child's name will be deleted from the recording. All audio and video recordings will be stored in a locked cabinet in a room where access is limited to research personnel.

If your child is identified as having difficulty with language but age-appropriate hearing and nonverbal reasoning, then he or she will be invited to participate in the treatment research study. At that point, 2 attention tests will be given.

- The *sustained attention test* requires your child to cross out as many pictures as possible that match a targeted picture in a certain amount of time.
- The *Stroop test* requires your child to find as many sets of matching color images as possible in 45 seconds.

If your child's articulation is below the 16th percentile, then your child will be asked to perform a repetition task to examine how the child pronounces vocabulary words.

- The *vocabulary repetition task* will require your child to repeat each of the words to assess your child's articulation of the 60 words.

Interactive Book Reading Treatment: In this study, your child will be taught 60 new words through book reading. Throughout the course of treatment, your child will be read 10 storybooks. Treatment will be broken into two parts. In the first part, your child will be taught 30 words in 5 storybooks. In the second part, your child will be taught the other 30 words in 5 new storybooks. Each story book will contain 6 words that are likely to be new to your child. The words are taught by reading the book and expanding on the text to help your child learn the words. The teaching involves providing a definition of the word, a synonym (i.e., a word with a similar meaning), and an example sentence. The new words are taught before reading the book, during book reading, and after book reading. During each book reading visit, children will be checked for learning of new words by a short picture pointing and naming exercise.

Your child will be randomly assigned to a particular treatment schedule for Part 1 and for Part 2. Treatment schedules vary based on the number of times your child hears each word during a book reading session (i.e., 4 times, 6 times, or 9 times) and the number of times your child reads each book (i.e., 4 times, 6 times, or 9 times). In each schedule, your child will hear each of the 60 words a total of 36 times. Sessions will be scheduled two to three times per week. You will be told your child's assignment, including the exact number of sessions and weeks. The assignment cannot be changed.

Treatment Schedules:

	Schedule 1	Schedule 2	Schedule 3
# of times child hears word during session	4	6	9
# of times each book is read	9	4	6
Total # of times child hears each word	36	36	36



Your child's learning of the 60 words will be examined prior to, during, immediately following treatment, and again 2 weeks following the treatment. When not tested during treatment, there will be special vocabulary test sessions. See Time Summary Table above.

- The *vocabulary definition task* will require your child to explain the meaning of each word.
- The *vocabulary naming task* will require your child to say the name of a picture illustrating each word.

Recordings: If administered, the repetition task will be audio recorded and used to transcribe your child's responses. All other tasks and treatment sessions will be video recorded and used to document your child's performance during testing and treatment and will be used to document the length of each session. Audio and video recordings may be used to train research assistants and undergraduate/graduate students in research or speech-language pathology procedures. If these recordings are used for teaching purposes, your child's name will be deleted from the recording. All audio and video recordings will be stored in a locked cabinet in a room where access is limited to research personnel.

RISKS

The potential for risks, stress, or discomfort is largely non-existent. It is possible that your child may become bored or tired during testing or treatment sessions. Children will be given breaks if this occurs. You are invited to observe all sessions.

BENEFITS

In terms of direct benefits, you will be given a written report detailing your child's performance on all standardized clinical tests administered during the preliminary evaluation which may be useful in educational and clinical planning. In addition, participation in this research program may help to improve your child's vocabulary because he/she may learn some of the 60 words taught. In terms of indirect benefits, the findings from this study will be used to improve treatment options for children with SLI.

PAYMENT TO PARTICIPANTS

You may be compensated up to \$75 for completion of the entire study. The first payment will be made after the Preliminary Evaluation is completed (\$25.00). Then, if your child qualifies for the study, an additional payment of \$25.00 will be after the vocabulary test that occurs 2 weeks after the first part of treatment (Part 1 Completion). The last payment of \$25.00 will be made upon completion of the entire study.

\$25.00	Preliminary Evaluation
\$25.00	Part 1 Completion
+ \$25.00	Completion of the Study
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\$75.00	

Investigators will ask for your social security number in order to comply with federal and state tax and accounting regulations.



INFORMATION TO BE COLLECTED

To perform this study, researchers will collect information about your child. This information will be obtained from a history questionnaire completed by you during the preliminary evaluation. Also, information will be collected from the study activities that are listed in the Procedures section of this consent form. Your child's name will not be associated in any publication or presentation with the information collected about your child or with the research findings from this study. Instead, the researcher(s) will use a study number or a pseudonym rather than your child's name.

The information collected about your child will be used by: Dr. Holly Storkel (principal investigator), members of the research team, KU's Center for Research and officials at KU that oversee research, including committees and offices that review and monitor research studies. In addition, Dr. Storkel and her team may share the information gathered in this study, including your child's information, with: collaborating researchers, colleagues, and representatives of the National Institutes of Health (the sponsor of the study). The purpose of these disclosures is to facilitate completion of the research (e.g., analysis of the collected data) and safety monitoring. Again, your child's name would not be associated with the information disclosed to these individuals. Some persons or groups that receive your health information as described above may not be required to comply with the Health Insurance Portability and Accountability Act's privacy regulations, and your health information may lose this federal protection if those persons or groups disclose it.

The researchers will not share information about you with anyone not specified above unless (a) it is required by law or university policy, or (b) you give written permission.

Permission granted on this date to use and disclose your information remains in effect indefinitely. By signing this form you give permission for the use and disclosure of your child's information, excluding your child's name, for purposes of this study at any time in the future.

REFUSAL TO SIGN CONSENT AND AUTHORIZATION

You are not required to sign this Consent and Authorization form and you may refuse to do so without affecting your right to any services you are receiving or may receive from the University of Kansas or to participate in any programs or events of the University of Kansas. However, if you refuse to sign, your child cannot participate in this study.

CANCELLING THIS CONSENT AND AUTHORIZATION

You may withdraw your consent to allow participation of your child 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: Dr. Holly L. Storkel, at Department of Speech-Language-Hearing, 1000 Sunnyside Avenue, 3001 Dole Center, Lawrence, KS 66045-7555 (785-864-0497; 785-864-4873; hstorkel@ku.edu).

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.

QUESTIONS ABOUT PARTICIPATION

Questions about procedures should be directed to the researcher listed at the end of this consent form.

PARTICIPANT CERTIFICATION

I have read this Consent and Authorization form. I have had the opportunity to ask, and I have received answers to, any questions I had regarding the study and the use and disclosure of



information about my child for the study. I understand that if I have any additional questions about my rights as a research participant, I may call (785) 864-7429 or write the Human Subjects Committee Lawrence Campus (HSCL), University of Kansas, 2385 Irving Hill Road, Lawrence, Kansas 66045-7568, e-mail irb@ku.edu.

I agree to allow my child to take part in this study as a research participant. By my signature I affirm that I am at least 18 years old and I have received a copy of this Consent and Authorization form.

Type/Print Participant's Name

Date

Parent/Guardian Signature

Researcher Contact Information

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