This is the consent form & assent script for the study entitled
"Retrieval-Based Word Learning in Developmental Language Disorder During Book Reading"
NCT06026124

6/7/2023

RESEARCH PARTICIPANT CONSENT FORM
Retrieval-based Word Learning
Principal Investigator: Laurence B. Leonard, PhD
Department of Speech, Language, & Hearing Sciences
Purdue University: West Lafayette location

Key Information

Please take time to review this information carefully. This is a research study. Your child's participation in this study is voluntary which means that you or your child may choose not to have your child participate at any time without penalty or loss of benefits to which you are otherwise entitled. You may ask questions of the researchers about the study whenever you would like. If you decide to have your child take part in the study, you will be asked to sign this form. Be sure you understand what you will do and any possible risks or benefits. The purpose of this study is to understand how children learn new words. The duration of the study will be 1 session to determine if your child is eligible. These sessions will last approximately 60 minutes each. If your child qualifies, there will be an additional 5 sessions that will each last approximately 60 minutes.

What is the purpose of this study?

We are asking you to participate in this study so that we can examine how children learn new words. We would like to enroll 490 children in this study.

What will I do if I choose to be in this study?

We will ask your child to participate in a variety of activities. These involve looking at pictures and listening to sentences presented on a computer. Novel (made-up) words will be used to label pictures of unfamiliar plants and animals. We will ask your child to point to pictures and to use the novel words to label pictures. In addition, some standardized tests of language, speech and cognitive abilities will be administered to obtain more information about your child. All sessions will be audiorecorded and/or videorecorded.

How long will I be in the study?

The research activities will take place at our lab at Purdue University in 6 one-hour sessions. Over the course of the study, there will be two points at which sessions will be scheduled on back-to-back days. Otherwise, they will be scheduled weekly at mutually convenient times. Each of the periods will be broken up into smaller segments to prevent fatigue and boredom.

What are the possible risks or discomforts?

There is a risk of breach of confidentiality. However, we do a lot to minimize this risk, as outlined in the Confidentiality section. The activities that your child will participate in do not have any more risks than what he/she would encounter in everyday activities. In-person research carries with it the risk of contracting a communicable illness. However, precautions will be taken to minimize this risk at all times. You may choose to have your child wear a mask, but s/he will be asked to remove it for short periods to record verbal responses.

Are there any potential benefits?

Your child will not benefit directly from the research activities. The research activities are not intended for diagnosis or treatment purposes. However, when we have finished, we will provide you with a report, summarizing test scores and other information about your child that we gained during the research activities.

Will I receive payment or other incentive?

Your child will be tested in 1 session to determine if he/she meets the criteria to participate in this study. If your child does not qualify, you will be paid $15.00 for each of the testing sessions as compensation for your expenses in bringing the child to the testing site and your child will receive a small toy after each session. If your child does qualify, you will be paid $15.00 for each of the testing sessions and will be offered the opportunity to continue participation in the research project. If you choose to have your child continue, you will be paid $15.00 for each of the remaining 5 1-hour research periods and your child will receive a small toy after each session. There is no compensation for your child's participation in the therapy and play activities (and no fee is charged).

Parent Initials _____ Date_____ Researcher Initials _____ Date _____

Parent Initials _____ Date_____

Will information about me and my participation be kept confidential?

This project is funded by the National Institutes of Health (NIH). The project's research records may be reviewed by departments at Purdue University that oversee research, or by the NIH, to make sure those participants' rights are being protected. All the research activities will be audio- and/or videorecorded to check the accuracy of our transcription of your child's responses. The identity of all participants will remain private. Data for those children who are not eligible for the study will be destroyed immediately.

We assign an identification number to each child in the study; all records, data, and publications will contain only this ID number. All data will be stored, using the same ID system, in file cabinets in a locked laboratory in Lyles-Porter Hall (rooms 3132, 3172, 3182) or on password protected computers. The participant ID key will be separated from the data in a locked file cabinet in LPH 3182. The data will be used in the present research project and will be archived for use in future associated projects. Three years after all related publications are completed, we will destroy the data and participant ID key. Paper data will be shredded and electronic records erased. Only the research team directly involved with the project will have access to the data.

In order for us to compensate you for your expenses using a Purdue-issued check, we will submit your name, social security number and address to the business office of Purdue University using a secure file sharing system.

This study meets the NIH definition of a Clinical Trial. As such, a description of this clinical trial will be available on 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 Website at any time.

Sometimes it is helpful for us to be able to play audio-or videorecordings of children when we discuss our research in the classroom or at professional meetings. In such cases, we ensure that the child's name is not used on the recording. Place an "X" on the line below that indicates your preference regarding the use of audio- and/or videorecordings for this purpose.

___ I voluntarily give my consent for audio- and/or videorecordings of my child to be used.

___ I do not give my consent for audio- and/or videorecordings of my child to be used.

Parent Initials _____ Parent Initials _____

We would like your permission to contact you about future studies in our lab. When we contact you, we would provide information about the study so that you can decide whether you want your child to participate. You may, at any time, withdraw your permission to be contacted. Place an "X" on the line below if interested:

_____ Yes, you may contact me about future studies.

Certificate of Confidentiality

"This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. For additional information about CoCs see http://grants.nih.gov/grants/policy/coc/faqs.htm.

Parent Initials _____ Date_____ Researcher Initials _____ Date _____

Parent Initials _____ Date_____

What are my rights if I take part in this study?

You do not have to participate in this research project. If you do agree to participate you can withdraw your participation at any time without penalty. At each session, we will ask your child for his/her verbal consent to participate (e.g., "Do you want to play the listening game today?"). If your child does not give consent, we will postpone the activity and try again later. If at any time during a research activity, your child gives verbal or non-verbal indication of a refusal to continue, we will stop the activity and try again later.

Who can I contact if I have questions about the study?

If you have any questions, comments, or concerns about this research project, you can talk to one of the researchers: P.I. Dr. Laurence B. Leonard, at (765) 494-3794 or Pat Deevy at (765)496-1821, deevy@purdue.edu. If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, contact the Human Research Protection Program (HRPP) at Purdue University at (765) 494-5942, irb@purdue.edu or write to HRPP, Ernest C. Young Hall, 10th Floor-Room 1032, 155 S. Grant Street, West Lafayette, IN 47907-2114. To report anonymously via Purdue's Hotline, see www.purdue.edu/hotline

Documentation of Informed Consent

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research study, and my questions have been answered. I am prepared to participate in the research study described above. I will receive a copy of this consent form after I sign it.

_____ _____

Parent/Legal Guardian's Signature Date

_____

Parent/Legal Guardian's Name

_____ _____

Parent/Legal Guardian's Signature

Date

_____

Parent/Legal Guardian's Name

_____

Child Participant's Name

_____ _____

Researcher's Signature Date

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Retrieval-based Word Learning
Principal Investigator: Laurence B. Leonard, PhD
Department of Speech, Language, & Hearing Sciences
Purdue University: Indianapolis location

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We will ask your child to participate in a variety of activities. These involve looking at pictures and listening to sentences presented on a computer. Novel (made-up) words will be used to label pictures of unfamiliar plants and animals. We will ask your child to point to pictures and to use the novel words to label pictures. Your child will also watch videos in which characters do novel actions described by novel verbs. He/she will then be asked to describe actions using the novel verbs. In addition, some standardized tests of language, speech and cognitive abilities will be administered to obtain more information about your child. All sessions will be audiorecorded and/or videorecorded.

How long will I be in the study?

The research activities will take place at our lab at the Indianapolis location of Purdue University's SLHS laboratories (8445 Keystone Crossing) in 6 one-hour sessions. Over the course of the study, there will be two points at which sessions will be scheduled on back-to-back days. Otherwise, sessions will be scheduled weekly at mutually convenient times. Each of the periods will be broken up into smaller segments to prevent fatigue and boredom.

What are the possible risks or discomforts?

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We assign an identification number to each child in the study; all records, data, and publications will contain only this ID number. These data will temporarily be stored, using the same ID system, in locked file cabinets or on password protected computers at the Keystone Crossing location until they can be transported to Purdue's campus. There they will be stored in file cabinets in a locked laboratory in Lyles-Porter Hall (rooms 3132, 3172, 3182) or on password protected computers. The participant ID key will be separated from the data in a locked file cabinet in LPH 3182. The data will be used in the present research project and will be archived for use in future associated projects. Three years after all related publications are completed, we will destroy the data and participant ID key. Paper data will be shredded and electronic records erased. Only the research team directly involved with the project will have access to the data.

In order for us to compensate you for your expenses using a Purdue-issued check, we will submit your name, social security number and address to the business office of Purdue University using a secure file sharing system.

This study meets the NIH definition of a Clinical Trial. As such, a description of this clinical trial will be available on 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 Website at any time.

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Parent/Legal Guardian's Signature Date

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Parent/Legal Guardian's Name

_____ _____

Parent/Legal Guardian's Signature

Date

_____

Parent/Legal Guardian's Name

_____

Child Participant's Name

_____ _____

Researcher's Signature Date