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INFORMED CONSENT DOCUMENT

Project Title: **Language outcomes, mechanisms, and trajectories in adults with and without Developmental Language Disorder**

Principal Investigator: **Kristi Hendrickson**

Research Team Contact: **Kristi Hendrickson**
319-335-8701

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you participated in a study of language development here at the University of Iowa when you were a child. The purpose of this research study is to investigate how language develops from childhood all the way to adulthood.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 450 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last approximately 6.5 hours over the span of two visits.

WHAT WILL HAPPEN DURING THIS STUDY?

In your first visit, which will be conducted virtually over Zoom, you will be asked to fill out a short demographics questionnaire to obtain basic demographic information in order to provide an overview of study participants. You will also take a series of language tests, surveys, and questionnaires, which will assess your language abilities. You will hear words and point to pictures, say different words aloud, and listen to a few short paragraphs. We will also ask you questions about your language. These tests will take approximately 2 hours.

In your second visit, which will last approximately 4.5 hours, you will come to the Wendell Johnson Speech and Hearing Center at the University of Iowa and complete more language tests like the ones described above. In the second visit you will also participate in three eye-tracking tasks. For this task, you will be asked to view a series of pictures and listen to and say words. You will make simple perceptual decisions in response to these stimuli. These may include matching pictures with words or identifying pictures or sounds. During this procedure, an eye-tracking camera will be used to determine

where you are looking on the screen. The camera will be adjusted to your eyes, and you will be asked to look at a number of locations on a computer screen while data is recorded by the eye-tracker.

At the end of the session, we will talk to you about the study and ask if you have any questions.

Data collected as part of you participation in previously related studies will be used for analysis in this study. This data includes data from language samples (i.e., conversations you had with the experimenter), and a battery of language tests.

Audio and Video Recordings

One aspect of this study involves making audio and video recordings. A video camera will record you when you are participating in some of the language tests described in the section above. This is for scoring and transcription purposes only, and only research staff will have access to these recordings. The recordings will be destroyed at the end of the project.

[ ] Yes [ ] No I give you permission to make audio and video recordings of me during this study.

DATA STORAGE FOR FUTURE USE

As part of this study, we are obtaining data from you. We would like to study your data in the future, after this study is over without further consent. Your data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it may be stripped of identifiers (such as name, date of birth, address, etc).

The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding adult language abilities, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products or tests that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of data do not retain any property rights to the materials. There are no plans to provide financial compensation should this occur.

Your data will be stored with a code which may be linked to your name and would enable us to identify which data are yours. If you agree now to future use of your data and your contact information but decide in the future that you would like to have it removed from future research, you should contact **Kristi Hendrickson at (319) 335-8701**. However, if some research with your child's data has already been completed, the information from that research may still be used.

We may also keep your contact information (email address and/or phone number) to inform you about our future studies. In such cases, your agreement for your participation in the current study does not obligate you to participate in our future studies. A separate consent document needs to be signed for future studies.

WILL I BE NOTIFIED IF MY DATA RESULT(S) IN AN UNEXPECTED FINDING?

The results from the data we collect in this research study are not the same quality as what you would receive as part of your routine health care. The data results will not be reviewed by a physician who normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your data will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your child's primary care physician.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

These research tasks present no more than the minimal risk associated with many everyday activities. These tasks involve no pain or invasive procedures. When taking the language tests described above, you may experience discomfort because some tasks may be difficult or boring at times. To minimize boredom and fatigue during language tests, you are encouraged to take breaks as needed, and are only asked to do your best.

Minor risks may also include slight discomfort from the eye-tracker, and further, there may be a risk of loss of confidentiality of data. To minimize these risks, you will be given opportunities to take breaks during the study, and all data will be stored on password-protected computers and/or kept in a locked filing cabinet in the Psycholinguistics Lab.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from participating in this study; however, we hope that, in the future, other people might benefit from this study because the information we learn may be helpful in treating individuals who have language challenges.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs associated with being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be compensated with $20 per hour for participation in this study. Further, you will be reimbursed for gas and parking. You will receive a check in the mail after the study is completed. Finally, if you are coming from a distance greater than 2 hours, we will provide hotel accommodations.

WHO IS FUNDING THIS STUDY?

The National Institute on Deafness and Other Communication Disorders (NIDCD) is funding this study. This means that the University of Iowa is receiving payments from NIDCD to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIDCD for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.

- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.

- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WILL YOU KEEP MY NAME ON FILE TO GIVE TO OTHERS?

We will keep information about you in a special kind of computer listing called a registry. A registry keeps information about you on file so that *other* researchers, not involved in this particular study, may contact you in the future about whether you are interested in being in *different* research studies. The registry will contain information such as your name, address, age, and selected medical information such as diagnosis and treatment. We will keep the information in this registry secure by only allowing lab members to have access to the information, which will be kept in a locked filing cabinet in a locked laboratory. You may request that your personal information be removed from this file at any time by contacting **Kristi Hendrickson at (319) 335-8701.**

[ ] Yes [ ] No I give you permission to put my and my child's name and personal information in a registry so that other researchers can contact me in the future about different research studies.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will only collect the minimum amount of private information necessary to run the study. On most forms, your name will be replaced with a subject ID number. Any forms including your name will be stored separately from the experimental data, and any files linking names to your ID number will be stored in a locked filing cabinet. All electronic files are stored on password-protected computers in a locked laboratory office. Only members of the research team will have access to the files, both paper and electronic, in the laboratory. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose to not take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact **Kristi Hendrickson at (319) 335-8701.** If you experience a research-related injury, please contact **Kristi Hendrickson at (319) 335-8701.** If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office website, http://hso.research.uiowa.edu/. To offer input about your child's experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

_____
(Subject's Name - printed)

_____ _____
(Subject's Signature) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)