

UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Leading & Reading Acquisition

Company or agency sponsoring the study: University of Michigan and the National Institute of Health (NIH)

Names, degrees, and affiliations of the principal investigator:

Principal Investigator: Ioulia Kovelman, Ph.D., Associate Professor of Psychology, University of Michigan

1.1 Key Study Information

You, or your child, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a child's participation in the research, note that in the sections that follow the word 'you' refers to 'your child'. This form contains information that will help you decide whether to join the study. All of the information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

This research collects information to better understand how children and adults speak and read.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include fatigue and frustration. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by informing scientists, educators and clinicians. More information will be provided later in this document.

We expect the amount of time you will participate in the study will 4 hours.

You can decide not to be in this study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of the study is to uncover the how we learn to speak and to read. To answer this question, we study individuals who speak only one language, multiple languages, and those who have a history of language-based learning impairments.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Anyone can participate. We invite those who speak English and/or other languages. We also invite those who have a history of language or reading impairments.

3.2 How many people are expected to take part in this study?

1760 people are expected to participate.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

The study will involve the following steps, in the order listed:

- 1) Background Questionnaires. First, we will ask you questions about your developmental history, such as what language(s) you speak at home and when you learned to speak those languages.
- 2) Language and Cognitive Assessments. During the visit, we will ask you or your child to complete tasks measuring your language, literacy, and cognitive ability. During the tasks we will ask you or your child to pay attention to visual symbols, read words and sentences as well as to listen to sounds, words and sentences.
- 3) Computer Games. During the visit, you will be asked to complete language and cognitive tasks presented on a computer. During the games, we will ask you to pay attention to visual symbols, read words and sentences as well as to listen to sounds, words and sentences.
- 4) fMRI Imaging. fMRI is an FDA-approved neuroimaging method and is safe for use with children and adults who do not have metal implants. We measure how the brain works while children or adults complete computer games described above. We may also measure the structure of your or your child's brain while you or your child wear a cap with vitamin-E capsules.

4.2 How much of my time will be needed to take part in this study?

The visit will last about 4 hours.

4.3 When will my participation in the study be over?

Your participation in this study will be over at the end of the visit.

4.4 What will happen with my information used in this study?

Your collected information may be shared with University of Michigan and National Institute of Health (NIH).

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are fatigue and frustration during this study. If this happens, we will address the situation right away. As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, your child may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researcher, Ioulia Kovelman (kovelman@umich.edu or 734-647-3712) about any injuries, side effects, or other problems that your child has during this study. You should also tell your regular doctors.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study, but your participation may help inform educators and clinicians on better methods of diagnosis and remediation of language and reading impairments.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Since participation in this study is entirely voluntary, you have the alternative option of not participating, in which case there will be no penalty, and you will be compensated for the time you did spend participating in the study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you or your child. Neither you nor your child will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

You are free to leave the study at any time. Simply indicate your choice to the researcher. There are no dangers in leaving the study early.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because your child is in the study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

Your child will be paid \$10 per hour with a gift card and will also receive small gifts (bubbles, etc.) for participating at the end of the session.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Study records that contain subject names will have access limited to the Principal Investigator. Confidentiality will be preserved for participants by coding all study data, images, and test results with an identifying number, and referring to this number in all analyses. You and your child will not be identified in any reports on this study. Your participation in this study is also kept completely confidential; any paperwork (such as this consent document) containing your name or other identifying information is stored in locked cabinets in locked offices, with access limited to the study team.

Although we assure you that everything you tell us will remain confidential, there are some circumstances where the law requires that we may need to break this assurance in order to prevent somebody from getting hurt. For example, if you tell us something that leads us to believe that you might harm yourself or others, e.g. from suicidal feelings, or harm may come to somebody in the future, e.g. ongoing abuse of a minor or vulnerable adult, then we may need to alert proper authorities. Furthermore, all study staff are trained in the proper handling and storage of confidential information and study records.

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DO NOT CHANGE THIS FIELD—IRB USE ONLY

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.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of suicidal harm, potential harm of others, and abuse of a minor or vulnerable adult.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
 - Make sure the study is done safely and properly
 - Learn more about side effects
 - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.

- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over, or if I leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Ioulia Kovelman, PhD

Mailing Address: University of Michigan, Department of Psychology, East Hall, 530 Church Street,
Ann Arbor, MI 48109

Telephone: (734) 647-3712

E-Mail: kovelman@umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)

2800 Plymouth Road

Building 520, Room 3214

Ann Arbor, MI 48109-2800

Telephone: 734-763-4768 (For International Studies, include the appropriate [calling codes](#).)

Fax: 734-763-1234

e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. *(Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- Other (specify): _____

12. SIGNATURES

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent to audio recording and photography solely for purposes of this research

This study involves audio recording and photography. If you do not agree to be recorded, you can still take part in the study.

_____ Yes, I agree to be audio recorded and photographed.

_____ No, I do not agree to be audio recorded and photographed.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Legally Authorized Representative or Parent Permission

Subject Name: _____

Parent/Legally Authorized Representative:

Printed Legal Name: _____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: ☐ Parent ☐ Spouse ☐ Child ☐ Sibling ☐ Legal guardian ☐ Other

If "Other," explain: _____

Reason subject is unable to consent: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Permission to recontact for future studies

If you are willing to be contacted for future studies conducted in our lab, please check the appropriate box below. Checking this box means that the investigators involved in this project may use the information you give us here to re-contact you about future research studies. We will not share this information with investigators outside of this project. This form will be kept in a locked cabinet, to which only authorized personnel have access. The information that identifies you will be kept separate from your responses to the questionnaires and surveys you complete for this study. If you agree to future contact, and then change your mind, you may contact us at any time (see Section 10) to be taken off our list of potentially interested research subjects.

_____ Yes, you may contact me to provide information about future studies (does not obligate you to participate in any studies)

Preferred contact is: Phone _____ Email _____

_____ No, please do not contact me (checking this box does not prevent you from participating in this study)

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____