Neural Mechanisms of Successful Intervention in Children with Dyslexia

Informed Consent Form

NCT04323488

October 31, 2023

IRB Use Only
Approval Date: October 31, 2023
Expiration Date: October 31, 2024

STANFORD UNIVERSITY CONSENT FORM
Stanford University Reading & Dyslexia Research Program

Please check all that are applicable:
☐ I am an adult participant in this study.
☐ I am the parent or guardian granting permission for a minor in this study.

Filling out this general consent form means that you are consenting to have [your/your child's] information stored in our database so we can contact you about studies [you/your child] may be eligible for. You are **NOT** consenting to [have your child] participate in our studies.

Please note that filling out this general consent form does not guarantee participation in our studies. A research staff member will only contact you if [you are/your child is] eligible for any of our studies. If [you are/your child is] eligible for our studies, then [you/they] will go through a separate consent process for that study.

Please enter your email address:

Your email will only be used to send you a copy of your completed general consent form and information about studies [you are/your child is] eligible for.

Email address: _____
Confirm your email address: _____

Please confirm that you've read all the information above. Any questions about this consent form can be sent to our email: readingresearch@stanford.edu. If you no longer wish to fill out this general consent form, you may stop at any time.

☐ I have read all the information above .

PURPOSE OF RESEARCH

[You are/your child is] invited to participate in a research study of the neurobiological basis of learning to read, why some individuals struggle with learning to read, and how education programs can help individuals overcome their struggles. This study will create a large database of subject information that allows researchers to investigate interactions between many different skills and abilities thought to relate to reading ability. This database will be used for future recruitment, long-term data storage, and data analysis for research now and in the future.

If you decide to terminate [your/your child's] participation in this study, you should notify Jason D. Yeatman PhD at (650) 321-7553.

VOLUNTARY PARTICIPATION

[Your/Your child's] participation in this study is entirely voluntary. [Your/Your child's] decision not to participate will not have any negative effect on [you/your child] or [your/their] medical care. [You/your child] can decide to participate now but withdraw [your/their] consent later and stop being in the study without any loss of benefits or medical care to which [you are/your child is] entitled.

DURATION OF STUDY INVOLVEMENT

[You/your child] may be asked to complete between 1 and 15 sessions between 1 to 4 hours long. Signing this consent form means that we will follow up with you about study specifics and does not mean that [you have/your child has] to participate in all these sessions. In some cases, we may just invite [you/your child] to participate in one study. You will be asked to sign a separate consent form outlining the other tests that [you/your child] will be asked to complete as part of the Stanford University Reading & Dyslexia Research Program (RDRP).

Data Analysis: Large-scale analysis of data from many subjects will provide researchers an opportunity to explore complicated relationships overlooked in small studies. Building a large database of individuals with diverse reading abilities is a central mission of our program and we hope to support research efforts beyond those in our lab. Data collected as part of this study may be used for many years to help discover trends in the population and explore changes

due to development, education, and intervention. In addition, coded data may be shared online or with collaborators to allow for new and unforeseen discoveries.

Publications: Researchers may choose to include data in publications to support findings, or they may choose to release data alongside findings for replicability. All efforts will be made to ensure that [your/you and your child's] identity will not be revealed through the data included. For example, we might publish brain images for other researchers to work with, but we will never release [your/you and your child's] name. Therefore, we consider this data "coded" meaning that it is useful for research but not directly linked to any individual. However, it is always possible that coded data will become identifiable in the future through some unforeseen means. We take every step we can to mitigate this risk, but we have to acknowledge that it is a possibility. We want to make sure that [you/you and your child] consider this possibility before deciding to participate in this study.

PROCEDURES

If [you are/your child is] eligible for a study, the Protocol Director and his research study staff will reach out to you via email or phone to invite [you/your child] for an online or in-person visit. You will have the option of booking an appointment via email, phone, or an online booking calendar. You will receive consent forms via email and sign consent forms electronically. You will also receive confirmations and reminders via email, and in some cases, receive text message reminders as well. Please be aware that emailing and text messaging are not completely confidential modes of communication. If the email address that you initially provided us with is not secure (e.g. a "gmail" account) and you have a secure email account (e.g., an ".edu" address) that you would like to use instead, you may request for us to update this information in our system.

We may assess [you/your child] on cognitive, language, and reading skills. You may also be asked to complete questionnaires for demographic information, environmental factors, educational experience, and behavioral ratings. Some studies involve neuroimaging procedures such as Magnetic Resonance Imaging (MRI). In addition, some studies may involve intervention programs and/or computer-based activities. You will be asked to sign additional consent forms in order to participate in specific projects you may be invited to.

PARTICIPANT RESPONSIBILITIES

As a participant, [your/you and your child's] responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep [your/your child's] study appointments. If it is necessary to miss an appointment, please contact the research study staff to reschedule as soon as you know [you/your child] will miss the appointment.
- Receive emails and text messages.
- Notify us if you are expecting emails from Stanford RDRP but are not receiving the messages.
- Complete all consent forms and questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Jason D. Yeatman PhD at (650) 321-7553.
The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

Risks of collecting personal information through discussion or questionnaires:

One potential risk is breach of confidentiality related to the collection of sensitive medical information. Several precautionary steps are taken to ensure the protection of confidential information and to minimize the possible breach of confidentiality. All personnel are carefully trained to keep protected health information private. There is a single encrypted and password protected file that links subject numbers to identifiable information. That information is only accessible to the trained research staff and the Principle Investigator. All testing and medical information gathered will only be identified by a subject number and will be kept in a safe locked file cabinet or a secure electronic data base, such as REDCap. Audio or video recordings of testing sessions may also be stored in this manner. Paper copies of test records and forms may be retained alongside digital copies. Digital copies of all data will be stored indefinitely.

If you report many problems about [your/your child's] behavior, including that [you have/your child has] suicidal thoughts or thoughts about self-harm, we will ask for permission to share this information with [your/your child's] doctor and will offer you information for further evaluation and treatment.

Risks of testing:
There are no physical risks of testing. Tests may make [you/you and your child] worry about [your/their] performance. We will tell [you/your child] about [your/their] general performance at the end of the testing. [You/your child] may become bored or restless in the testing. We provide breaks. [You/Your child] may also bring snacks. We remain very positive to encourage [you/your child] to complete all tests. In some circumstances, we will offer a small gift at the end of the testing.

Overall discomforts and inconveniences:
include travel to the site, boredom, anxiety, and other emotions. There may be other risks that are unforeseeable at this time.

Unforeseeable Risks:
The procedures in the present study may involve risks to [you/your child] that are currently unforeseeable.

POTENTIAL BENEFITS

[You/Your child] will not benefit directly from this study. However, [you/your child] may gain access to intervention or technology without paying the costs normally associated with these procedures. Or you may learn useful information about yourself and/or your child. There are no explicit or implicit guarantees of any change in reading skill or any other ability as a result of participation. Additionally, [you/your child] will get to experience science in action!

ALTERNATIVES

The alternative is not to participate.

PARTICIPANT'S RIGHTS

[You/You and your child] should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. [Your/You and your child's] identity and/or personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even coded information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn [your/you and your child's] identity if this study falls within its jurisdiction.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another

investigator for future research studies without additional informed consent from you.

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 specimens that may identify [you/you and your child] 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 specimens 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 National Institutes of Health 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/your child's] 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 if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

Authorization To Use Your Health Information For Research Purposes

Because information about you or your child's health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how [your/your child's] health information will be used or disclosed in the study. [Your/your child's] information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of the study is to examine neural and behavioral differences between individuals with dyslexia and typical readers. In addition, we aim to test the feasibility of reading intervention programs to see if these trainings improve reading and reading-related skills. [Your/Your child's] performance in this study may be compared to [your/their] family medical history, and early health history.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, [you/your child] will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of [your/your child's] health information (and to discontinue any other participation in the study) at any time. After any revocation, [your/your child's] health

information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using [your/their] information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of [your/your child's] health information in this study, you must write to: Jason D. Yeatman, PhD
Graduate School of Education
School of Medicine, Division of Developmental Behavioral Pediatrics
Center for Education Research at Stanford
520 Galvez Mall, Room 232
Stanford, CA 94305

What Personal Information Will Be Obtained, Used or Disclosed?

[Your/Your child's] health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, descriptive data such as name, medical record number, age, birth date, gender, ethnicity, SES/family demographics, contact information; neural imaging studies, past and current therapies; eligibility criteria such as level of comprehension, blindness, deafness; and developmental testing, psychological testing, behavioral reports, or other assessments of functioning.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose [your/your child's] health information in connection with this research study:

- The Protocol Director, Jason D. Yeatman
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose [your/your child's] health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- National Institutes of Health
- Researchers at The University of California San Francisco
- Food and Drug Administration (FDA)

[Your/Your child's] information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of [your/your child's] health information will end on December 31, 2035 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

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LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

FINANCIAL CONSIDERATIONS

Payment/Reimbursement
[You/Your child] will be paid for each session at a rate of up to $25/hr. Sessions involving an MRI will be paid at least $60. For studies that require multiple visits, you/your child can either be paid per visit or at the end of the entire study.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs
There is no cost to [you/your child] for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits.

Sponsor
The National Science Foundation, Microsoft, University of California San Francisco, and the National Institutes of Health are providing financial support and/or material for this study.

COMPENSATION FOR RESEARCH-RELATED INJURY

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, [you/your child] might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist [you/you and your child] in obtaining appropriate medical treatment. In the event that [you have/your child has] an injury or illness that is directly caused by [your/their] participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If [you/you and your child] have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Jason D. Yeatman PhD. You may contact him now or later at (650) 321-7553. You should also contact him at any time if you feel [you have/your child has] been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or [your/your child's] rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650) 723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant [you/you and your child] have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;

- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

You give consent for [your/your child's] audio recordings to be used to re-listen back to sessions, check scoring, and make notes about the session.
___Yes ___No

You give consent for [your/your child's] video recordings to be used to re-watch back to sessions, check scoring, and make notes about the session.
___Yes ___No

Signing your name means you agree to be in this study and that you will receive an electronic copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

If available*, please have the other parent or guardian fill out the information below.

** The IRB determined that the permission of one parent is sufficient in accordance with 45 CFR 46.408(b).*

_____ _____
Signature of Other Parent or Guardian Date

_____
Print Name of Other Parent or Guardian

_____
Authority to Act for Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

PARTICIPANT INFORMATION

_____
Name

_____
Child Name (If applicable)

_____
Phone Number

_____
Zip Code