MRI Parental Permission

TITLE: Dyslexia and the reading network

PRINCIPAL INVESTIGATOR: Kristi Clark, Ph.D.

DEPARTMENT: Neurology

We invite you to take part in a research study. Please take as much time as you need to read the consent form. Throughout this document, the word "you" may also refer to "your child." You may want to discuss it with your family, friends, or your personal doctor. You may find some of the language difficult to understand. If so, please ask questions. If you decide to participate, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn more about how the brain changes while children learn to read, especially children who have dyslexia. Children with dyslexia have an unexpected difficulty with reading despite instruction. This study will help us reach our long-term goal, which is to develop new and better ways to teach reading to children with dyslexia. We use a magnetic resonance imaging (MRI) test because it can take pictures of each child's brain as he or she is reading. We are inviting both children who have and do not have dyslexia to take part in this study. We want to see how the brains of children with dyslexia are different from the brains of children without dyslexia.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study and sign the consent form, you and your child will be asked to do the following things. It is possible that you may sign the consent form but not be able to participate in the study because your child is ineligible. Study procedures will be conducted at USC. At the end of the consent form you will be asked to indicate whether you wish to be notified about future dyslexia studies.

Total time for involvement in this study is approximately 3-4 hours including behavioral testing and the MRI scan. Behavioral testing for your child will last approximately 1.5 hours. Testing will be completed individually in a quiet testing room. As part of your child's participation, you will be asked to complete questionnaires on your child's memory, language and problem solving skills as well as any childhood problem behaviors. You will also be asked to complete a personal data questionnaire including medical, social, and academic information about your child. These activities will take place during one visit. After this time, you and your child's participation in the study will be complete.

During the visit, your child will be asked to complete MRI testing at the Dana & David Dornsife Cognitive Neuroscience Imaging Center at the University of Southern California. MRI is not a routine part of the evaluation for dyslexia. He or she will be asked to lie on a table that is moved into a large cylinder. Your child's head and shoulders lie on a special tray that makes it more comfortable and easier to lay still. The MRI scanner uses a magnet to make images (pictures) of the brain. No X-rays are

involved. The machine will make a loud noise. To reduce the noise, your child will be given headphones. The MRI scan takes about 1 hour but will be split into two parts. Your child will be able to watch a DVD during part of the scan and play games during the rest of the scan. The games involve responding to questions using a button box. There are no known harmful effects from the MRI scanner.

The hardest part of the scan is lying still. You may stay in the MRI room with your child during the MRI scan if you would like.

We will also ask your child to provide less than one-half teaspoon of saliva by spitting into a tube. The saliva sample will be used for genotyping in the current, and future MRI studies to look at how genes may affect the brain.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks or discomforts associated with MRI scans may include anxiety from being in a tight, enclosed space, or discomfort from staying still for too long. Should your child become anxious or agitated during the MRI scan, this research study will be immediately discontinued.

The sound of the MRI scanner can be loud. We will provide headphones to minimize the noise, but some people find the noise annoying.

The magnetism of the machine attracts certain metals; therefore, people with metals in them will be excluded from the study. The metal in dental fillings is less susceptible to magnetism and is therefore allowed. Your child will be asked about any potential sources of metal, and their pockets will be emptied prior to the study.

There is a small risk that people not connected with this study will learn your identity or personal information. We will do our best to keep all study findings confidential.

Your child may experience embarrassment and/or anxiety from the personal questions we will ask. They can skip any questions that make them uncomfortable.

INCIDENTAL FINDINGS

It is possible that the research procedures could find a possible medical problem that is unrelated to the purpose of this study and that you did not know about before. The magnetic resonance imaging (MRI) scan you will receive during the course of this study is for research purposes only. It is not a clinical scan intended for diagnostic or therapeutic purposes. The Dornsife Imaging Center is a research center. It is NOT a Clinical MRI facility in a hospital.

There are no neuroradiologists at the Dornsife Imaging Center; therefore the staff is unable to make any medical comments about your scan. Should you want to know if your scan is normal or abnormal; the staff will not be able to tell you. However, all structural scans obtained in normal research subjects are sent to a neuroradiologist for blind review.

In the rare event the neuroradiologist detects an abnormality s/he will be given your name and contact information and the name and contact information of the physician of your choice.

The neuroradiologist will contact you and/or your physician (per your preference) to discuss the findings and suggest further action. You will also be given the data of the structural images on a CD so you can further consult with your physician. You may decline the offer of receiving the images on a CD, but may not decline the required neuroradiology review. You will be responsible for the cost of any additional tests or related treatment.

Genotyping is not a medical diagnostic tool, and as such the results will not allow us to tell you that your child does or does not have dyslexia.

WILL YOUR INFORMATION BE KEPT PRIVATE?

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. The University of Southern California's Institutional Review Board (IRB) may review your records. The IRB is a research review board that is made up of professionals and community members who review and monitor research studies to protect the rights and welfare of research participants. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

We will assign you a code and use this code in study records instead of your name. This is done to protect your identity. Your study data may be shared with other researchers conducting similar research.

Finally, the researchers will disclose, without your consent, information that would identify you as a participant in the research project under the following circumstances: child abuse, elder abuse, and danger to self or others.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

There are no direct benefits to taking part in this study to you or your child, however taking part in this study may help in the understanding of reading and reading disorders.

WHAT OTHER OPTIONS ARE THERE?

An alternative to participating in this research study is not to participate.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

Your child will be paid $25 per hour, and receive a toy prize or Barnes and Noble gift certificate (approximately worth 25 dollars). You will also receive paid parking.

WHAT ARE THE COSTS?

All research tests and procedures provided to you for this research study are being paid for by the sponsor. Neither you and/or your health plan/insurance company will be

charged for the cost of any research tests or procedures that are being done for this research study.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

It is important that you tell the study's principal investigator, Kristi Clark, Ph.D., if you feel that you have been injured because of taking part in this study. You can tell her in person or call her at 323-442-7246. If you require medical care/treatment for an injury you experience while participating in this study, medical care/treatment will be provided. You and/or your health plan/insurance company will be billed for the cost of treatment for all injuries you may experience during your participation in the study, and you will be responsible for any co-payments and deductibles that are standard for your health plan/insurance coverage. The costs for this medical care/treatment will not be paid for by the study sponsor. However, by signing this form you have not given up any of your legal rights.

WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this research is VOLUNTARY. If you choose not to participate, that will not affect your relationship with USC (or USC Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at USC.

CAN YOU BE REMOVED FROM THE STUDY?

You may be removed from the study at any time, for example if you do not follow instructions, are found to be ineligible, or if the study is discontinued. If this happens, you will still receive payment for your time.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about the research, or in the event of research related injury or if you experience an adverse reaction, please immediately contact Kristi Clark. Kristi Clark can be reached at 323-442-7246. If you have questions, concerns, or complaints about the research and are unable to contact the research team, contact the Institutional Review Board (IRB) Office at 323-223-2340 between the hours of 8:00 AM and 4:00 PM, Monday to Friday. (Fax: 323-224-8389 or email at irb@usc.edu).

If you have any questions about your rights as a research participant, or want to talk to someone independent of the research team, you may contact the Institutional Review Board Office at the numbers above or write to the Health Sciences Institutional Review Board at LAC+USC Medical Center, General Hospital Suite 4700, 1200 North State Street, Los Angeles, CA 90033. You will get a copy of this consent form.

PERMISSION TO BE RECONTACTED ABOUT FUTURE DYSLEXIA STUDIES:

Please mark whether you wish to be recontacted about future dyslexia studies.

I agree to be recontacted by telephone about future research studies on dyslexia.

Yes _____ No _____

I agree to be recontacted by email about future research studies on dyslexia.

Yes _____ No _____

AGREEMENT:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to allow my child to take part in this study.

Name of Parent	Signature	Date Signed (and Time)

_____

Name of Child

I have personally explained the research to the research participant and answered all questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time)

If informed consent is obtained using the Short Form method (oral translation of this document in a language understood by the participant combined with the written Short Form in the participant's language), the witness must sign and date the informed consent below. A witness signature is required ONLY when the Short Form method is used. If you are not using the Short Form method to obtain consent, no witness is needed and you may leave this signature line blank.

Name of Witness	Signature	Date Signed