UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You or your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your or your child's participation in this study. If you decide for you or your child to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you or your child.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: The Learning Brain: Language Acquisition with Cochlear Implants

1.2 Company or agency sponsoring the study: University of Michigan

1.3 Names, degrees, and affiliations of the researchers conducting the study:
Xiaosu Hu, Ph. D., Research Investigator at Center for Human Growth and Development
Ioulia Kovelman, Ph.D., Associate Professor at the Department of Psychology
Anne-Michelle Tessier, Ph. D., Research Investigator at Center for Human Growth and Development

2. PURPOSE OF THIS STUDY

2.1 Study purpose: The purpose of this research is to understand the brain bases of language and hearing made possible by Cochlear Implants.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

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

3.1 Who can take part in this study?
Adults and children with and without cochlear implants can take part in this study.

3.2 How many people (subjects) are expected to take part in this study?
150 people are expected to participate; 50 adults without cochlear implants; 100 children - 50 with cochlear implants and 50 without.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
The fNIRS imaging is experimental technology that has not been approved by the FDA. The study will involve the following steps, in the order listed:

1) Language & Reading Assessments. Participants first complete a brief set of tasks of language, literacy, and cognitive development. These tasks involve reading words, saying words, naming pictures, completing sentences, and answering questions about language use.

2) Computer Games. Participants complete games that involve listening to two words, sentences and syllables. Participants receive explicit instruction and have opportunity to practice these games.

3) fNIRS Imaging. During the fNIRS imaging participants computer games that practiced in (#2) above. As always, the experimenter will provide ample instruction. Participants are seated comfortably in a chair. A comfortable hat is positioned around the head, and we place plastic optode probes into the hat. The optodes emit low-intensity near-infrared light, which is harmless.

4.2 How much of my time will be needed to take part in this study?
There will be a total of up to two visits, each visit lasting up to 2 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 session.

5. INFORMATION ABOUT 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 boredom and fatigue. If this happens, we will address the situation right away by offering a break, snacks, as well as stickers and cartoon breaks for children, please do not hesitate to ask.

The researchers will try to minimize these risks by:
fNIRS imaging has previously been safely used in multiple studies with no reported problems or damage occurring to the participants' cochlear implants. fNIRS uses light to measure brain activity and does NOT use any sort of electric or magnetic fields. If you have any questions or safety concerns, please do not hesitate to ask. Below are a couple brief excerpts from previous published studies involving fNIRS and cochlear implants.

"fNIRS techniques are compatible with other electrical or magnetic monitoring systems and therapeutic devices (i.e., pacemaker, hearing aids, cochlear implants, etc.)." (Quaresima, Bisconti, and Ferrari, 2012. Brain and Language, p. 82). M. Ferrari is an MD and a Biochemistry Professor.

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, there might still be problems or side effects, even when the researchers are careful to avoid them. Please tell the researcher, Xiaosu Hu (xiaosuhu@umich.edu or 734-647-3712) about any injuries, side effects, or other problems that you or 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 or your child. It may also affect the results of the studies. You or your child 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 or your child may not receive any personal benefits from being in this study, but your or your child's participation may help inform researchers and clinicians about the neural changes that occur with cochlear implants and how this may affect language.

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. OTHER OPTIONS

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?

Participants are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty or loss of 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?

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 or your child's best interest to stay in the study.
- ✓ You or your child becomes ineligible to participate.
- ✓ You or your child's condition changes and you or your child needs treatment that is not allowed while you are taking part in the study.
- ✓ You or your child 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. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you or your child 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?
You will be paid $40 per session for your participation at the end of the session. You may be asked to participate in two sessions. Each of these sessions can take up to two hours. For each session you will be paid $ 40. If you choose to withdraw from the session, you will still be paid $ 40 for your participation.

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.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your and your child's privacy and the confidentiality of your and your child's research records will be protected in this study.

9.1 How will the researchers protect my privacy?
Study records that contain subject names will be accessible only to the Principal and Co-Investigators. 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 child's 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 or your child tell us something that leads us to believe that you might harm yourself, 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.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
If your child has a cochlear implant, signing this form gives the researchers your permission to obtain and use information about your child for this study, and may be required in order for your child to take part in the study. Information about your child may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- All records relating to your child's hearing/cochlear implants.

There are many reasons why information about you or your child 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 your child can take part in the study.
- The researchers may need the information to check your child's 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 child's 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 or your child is. If your child's pictures will be used in any publications or presentations, the researchers will ask you for your separate written permission.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you or your child, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you or your child 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 your child is.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

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).

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: Xiaosu Hu
Mailing Address: University of Michigan, Center for Human Growth and Development, North Ingalls Street, Ann Arbor, MI 48109.
Telephone: 734-615-2137
Email: xiaosuhu@umich.edu

You may also express a 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: US Country Code: 001)
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 "Parental 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 for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

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

For use only if required by sponsor:

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

ID Number: _____

Legal Representative (if applicable)

Signature of person legally
authorized to give consent _____ Date _____

Name (print legal name): _____ Phone _____

Address: _____

Check Relationship to Subject:

☐Parent ☐Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: _____

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 the IRBMED.

Reason subject is unable to sign for self: _____

Permission to Re-contact 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.

Legal Name: _____

Title: _____

Signature: _____

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