

**COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A  
RESEARCH PROJECT  
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL**

**Study Title:** Multimodal, developmental examinations of perception and production of language and speech

**Principal Investigator:** Nicole Landi

**Funding Source:** Haskins Laboratories

**Invitation to Participate and Description of Project**

We invite you or your child to participate in our research project Multimodal, developmental examinations of perception and production of language and speech. This study examines how adults and children perceive and understand speech. If you or your child participate, you or he/she will be asked to participate in up to two sessions across two days which will require you to come to Haskins Laboratories. While most behavioral assessments will take place at Haskins Laboratories, optional locations of the parent's choosing for behavioral testing can be offered as an accommodation when requested (i.e. participants home, community meeting facility, library, etc). (Speech-Language Pathologists are mandated reporters within the states of Rhode Island and Connecticut. Mandated reporters are required by law to report if they suspect or have reasons to believe that a child is being abused or neglected, or if there are reasons to believe a child is being subjected to conditions that would reasonably result in harm to the child.) The purpose of this study is to learn more about the relationship between speech perception and speech production and the development of these skills over the life span.

You /your child is being asked to participate in several different assessments of speech perception and production. During the first session you will participate in an ERP/NIRS (event related potential/near infrared spectroscopy) study. During this session you or your child will be asked to listen to sounds and/or name pictures presented on a computer screen. While you or your child engage in these tasks you will wear an ERP cap, which is a damp sponge net placed over your head, and several NIRS optodes, which are small sensors placed in between the ERP net and fastened with a headband. The NIRS optodes and ERP net will allow us to look at you or your child's brain's response to the tasks. At the end of this session you or your child will be asked to speak some words into a straw while we measure how much air you produce during different types of sounds. After this session is complete we may ask you or your child to participate in a simple auditory discrimination task in which you will be asked some simple questions about sounds you hear. Additionally, during this session we may ask you or your child to take a few short behavioral assessments of reading and language skills and/or fill out a questionnaire about you or your child's language background.

If you choose to come back for the second session, or bring your child back for a second session you or your child will participate in a speech movement experiment, during which you or your child will say some words while small sensors are taped to your face and around you or

your child's lips – this allows us to measure lip movement during speech. During the speech movement experiment we will make a video tape. We may also take another airflow recording during the second session, make a few audio tape recordings of you or your child's speech for later acoustical analyses and have you or your child participate in a simple picture viewing study while your eye movements are monitored.

In order to decide whether or not you want to participate or if you want your child to participate in this research study you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, and any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you or your child want to participate; if so, you will be asked to sign this form.

### **Description of Procedures**

If you agree to allow your child to participate in this study or you participate in the study, you or your child will be asked to participate in the following over the course of two sessions:

- 1) Electrophysiology (EEG) & Near Infrared spectroscopy (NIRS) experiment which asks you or your child to listen to sounds and name pictures while wearing the ERP sponge electrode cap and NIRS optodes. EEG and NIRS are tools that allow us to record electrical and blood flow activity in your brain while you perform the speech or reading task. Neither of these techniques is painful.
- 2) Speak some words into a plastic straw while we record your airflow during speech.
- 3) Speak some words while we make audio recordings.
- 4) Speak some words while wearing small sensors taped near your lips and on your face to measure lip movement during speech and while we videotape your movements.
- 5) Listen to some sounds and answer questions about those sounds (e.g., do these two sounds sound the same to you)
- 6) Complete some short behavioral assessments and/or questionnaires that measure reading and language ability and ask about you or your child's language background.
- 7) Look at some pictures while we monitor you or your child's eye movements.
- 8) Listen to words and respond to whether the a visually present word in Chinese character matches or mismatches with the word of a spoken sentence.

### **Risks and Inconveniences**

#### **Testing Risks:**

There are no known risks to participants in the testing portion of this research project. Some children may feel fatigued during testing, and breaks will be given at regular intervals. The saline solution that the ERP cap is soaked in may cause some mild irritation but this usually subsides in a few minutes. During the motion capture procedure, tiny reflective markers are stuck near your

child's lips and jaw; although these are not large enough to be a choking risk, it is possible that your child might inadvertently eat a harmless non-food item.

### **Benefits**

Knowledge gained from this study may provide information to the scientific and educational committee that would further the understanding of speech production and perception and clinical interventions for individuals with difficulty perceiving or producing speech. .

### **Economic Considerations**

You will receive \$20 for you or your child's completion of the ERP experiment, which may also include a brief set of behavioral assessments and an auditory discrimination task, \$20 for completion of the NIRS experiment which may also include a brief set of behavioral assessments \$ 10 for completion of the airflow experiment and \$10 for completion of the optical imaging experiment. Families are expected to take care of their own transportation and food expenses, but parking will be covered.

### **Treatment Alternatives/Alternatives**

N/A

### **Confidentiality and Privacy**

All possible steps will be taken to assure confidentiality. Records are filed by random subject ID numbers and are kept in locked areas under the supervision of personnel involved in the study. No names will appear in any publication or be mentioned in any public place in connection with this project. Individuals who agree to participate in the study are given a study ID. This ID includes the study code followed by a number. The ID does not include any information that could be used to identify the individual such as birth date or initials. The research team will only use the unique identifier for downstream applications. If the participant decides to withdraw from the study they can contact the study team and request for their data be destroyed and not used in any further analysis by contacting the PI, Dr. Landi at 203-865-6163 x 278.

Representatives from the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

The information about your child's health that will be collected in this study includes:

- *The following information: partial written health history, EEG scan, NIRS scan*
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Information about your child and your child's health which might identify your child may be used by or given to:

- *Representatives from Yale University and the Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for insuring research compliance. These individuals are required to keep all information confidential.*
- *Study personnel, including the PI, co-Investigators and other investigators*
- *Study Coordinator and Members of the Research Team*

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

### **In Case of Injury**

If you or your child is injured as a result of participation in this study, emergency medical treatment will be provided. However, you or your insurance carrier will be expected to pay the costs of treatment. No additional financial compensation for injury or lost wages is available. You do not give up any legal rights by signing this form.

### **Voluntary Participation and Withdrawal**

You are free to choose not to participate or have your child participate and if you or your child do become a participant you are free to withdraw or withdraw your child from this study at any time during its course. If you choose not to have your child participate or if you withdraw it will not adversely affect your relationship with Haskins Labs.

### **Questions**

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

**Authorization and Permission**

I have read (or someone has read to me) this form and have decided to participate or have my child participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me or my child for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

or

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

*If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator [Nicole Landi, 203-865-6163 x 278]. If you have any questions concerning you or your child's rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688. If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203/436-3650.*

***THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX  
HAS BEEN COMPLETED IN THE HIC OFFICE***

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| <p>THIS FORM IS VALID THROUGH:<br/> <u>11-19-13</u></p> <p>HIC PROTOCOL #:<br/> <u>0911005949</u></p> <p>INITIALED:<br/> <u>CESB</u></p> |
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