Indiana University Informed Consent Statement for Research

Executive Function, Listening-Related Fatigue, and Functional Listening Abilities

You and your child are being asked to participate in a research study. This consent form will give you information about the study to help you decide whether you want you and your child to participate. It is your choice whether or not you want you and your child to be in this research study. Please read this form, and ask any questions you have (by calling 812-855-6271 or emailing careslab@iu.edu), before agreeing to be in the study.

The purpose of this study is to understand what makes daily listening challenging for children who are deaf/hard of hearing. Recent research has shown that a child's ability to pay attention, remember things, and stay organized (i.e., executive function) could be associated with their daily listening difficulty. We are interested in understanding if executive function abilities in children who are deaf/hard of hearing are linked with daily listening challenges.

We are asking you if you want you and your child to be in this study because your child has normal hearing or a known hearing loss.

The study is being conducted by Dr. Samantha Gustafson in the Department of Speech, Language and Hearing Sciences at Indiana University.

If you agree for you and your child to be in the study, the following will happen. As the parent/guardian/primary-caregiver for your child, you will be asked to complete four questionnaires about your child's daily listening difficulties and associated symptoms, about how they manage their thoughts, actions, and emotions, and about their hearing, health, and educational history. These questionnaires should take less than 60 minutes and can be completed via email, over the phone, in person, or via Zoom.

Your child will be asked to complete two questionnaires about their daily listening difficulties and associated symptoms and answer a handful of questions about their daily listening practices. This will be completed using an interview that will occur over Zoom or in the Children's Auditory Research for Educational Success (CARES) lab at Indiana University and should take 20-30 minutes.

Before agreeing to you and your child's participation, please consider the risks and potential benefits of them taking part in this study. Research studies are designed to obtain new knowledge. This new information may help people in the future. Below is a list of known risks of this study.

- You or your child may be uncomfortable while answering the survey questions. While completing the survey, any questions that make you uncomfortable or that you/they do not want to answer can be skipped.

- There is a risk someone outside the study team could get access to your child's research information from this study. Any personal information we collect will be stored in a secure, password-protected database. The data will be coded so that your and your child's name is not attached to the data.

You and your child will be paid for participating in this study. You and your child can earn up to $30 for participating - $15 for completing the child interview and $15 for your completion of the parent questionnaires.

How Will My Information be Used?

The study team may collect information about you from your medical records. This may include information that can identify you, such as your name, contact information, and medical record number. Information from your medical records will be used to make sure you meet the criteria to be in this study.

The information released and used for this research will include medical history/treatment, consultations, laboratory/diagnostic tests, operative reports, and diagnostic imaging reports.

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Indiana University Health Physicians (Primary Care, Pediatrics, Otolaryngology)
- IUMG – Primary Care Physicians
- Eskenazi Health
- Indiana Network for Patient Care (INPC)
- Hear Indiana
- Other:

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- State and Federal government agencies as permitted by law, including but not limited to:
    - Office for Human Research Protections (OHRP)

After your medical record information is released for purposes of this research study, your information may no longer be protected under federal privacy laws, such as HIPAA. However, your identifiable information will still be stored securely and only used as described in this consent.

We will protect you and your child's information and make every effort to keep their personal information private, but we cannot promise complete confidentiality. No information which could identify you or your child will be shared in publications about this study.

You and your child's personal information may be shared outside the research study if required by law. We also may need to share research records with other groups for quality assurance or data analysis. These groups include the Indiana University Institutional Review Board or its designees, and state or federal agencies who may need to access the research records (as allowed by law).

Information collected for this study may be used for other research studies or shared with other researchers who are conducting their own research studies. This may include sharing with researchers outside Indiana University and sharing with private companies. It may also include making the information available in public and private databases of research data so that other researchers can use the information to answer research questions.

If we share your information in this way, we will remove information that could identify you or your child, such as names and contact information, before any information is shared. Since identifying information will be removed, we will not ask for your additional consent for this sharing.

If you have questions about the study or encounter a problem with the research, contact the researcher, Dr. Samantha Gustafson, at 812-855-6271 or sjgustaf@iu.edu.

For questions about you or your child's rights as research participants, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

If you decide to allow you and your child to participate in this study, you can change your mind and decide to remove yourselves from the study at any time in the future. If you decide to withdraw your child, please tell us in person, over the phone, or by emailing Dr. Gustafson. If you withdraw them from the study, that means that we will not be able to collect new information about you or your child; however, we will keep the data unless you request that we destroy it.

We would like to communicate with you about this study by text message and/or email. We might use text or email to send you reminders about upcoming study visits, check on how you and your child are doing, or tell you about the progress of the research. Text messaging and email are not secure methods of communication. The information sent over text or email, which may include sensitive or personal information, could be accessed or read by someone other than you. If you would like us to communicate with you via text or email, please initial the lines below and provide the phone number(s) and/or email address(es) you would like us to use.

_____ I authorize the researchers to send me emails related to this research study

Email address for this communication: _____

_____ I authorize the researchers to send me text messages related to this research study

Phone number for this communication: _____

You can still participate in this study even if you do not want us to contact you by text or email.

Parent's Consent

Printed Name of Parent: _____

Signature of Parent: _____**Date**:_____