

**Vanderbilt University Institutional Review Board
Informed Consent Document for Research**

Principal Investigator: Fred H. Bess
Study Title: Listening Effort and Fatigue in School-Age Children with Hearing Loss
Institution/Hospital: Vanderbilt University School of Medicine

Revision Date: 09.12.13

This informed consent document applies to parents.

Name of participant: _____ Age: _____

We want to tell you about a research study. Please read this form carefully. Feel free to ask any questions you may have about this study. You will get to keep a copy of this consent form.

The Listening and Learning Lab at Vanderbilt Bill Wilkerson Center (VBWC) is completing this study.

We want to know more about listening fatigue for children with hearing loss and children with language impairment. We are inviting children ages 6 to 12 who are in one of the following categories.

- (a) bilateral hearing loss.
- (b) unilateral hearing loss.
- (c) language impairment.
- (d) typical hearing and language development.

What will my child and I do? Your child will participate in several research sessions.

Session 1: You and your child will come to the VBWC for Session 1. At this visit, we will do several activities. We will test your child's hearing. We will ask you some questions about your child, including race, medical/educational history, etc. We will test your child's language. We will also train you and your child how to do some activities for future sessions. Session 1 will last about 2 hours.

Session 2: We will ask you to swab your child's cheek at home on two separate days. We will teach you how to do this during Session 1. You can practice in the lab before you do it at home. We are interested in cortisol levels, a stress hormone. We will not be using these samples to obtain genetic information. We will also come to your child's school to swab your child's cheek on these same two days in the morning and in the afternoon. While we are at your child's school we will make measurements of the noise level in your child's classroom and ask some questions about how they feel. If your child's school requires further documentation regarding your child's participation, a copy of this form may be provided to school administrators and/or teachers.

Sessions 3 and 4: You and your child will come to the VBWC on two separate days. At each visit, your child will complete ERPs before and after several listening activities. ERP testing will involve recording your child's brain waves using soft sensors placed on your child's head. These sensors are arranged like a shower cap. Once the net is in place, your child will hear sounds from a loudspeaker and/or see pictures on a video screen. You can be in the room with your child or watch from an adjacent room. In the listening activities, your child will do things like listen to sentences and repeat words. Your child will also do things like watch screens of numbers and push buttons. Sessions 3 and 4 will last about 3 hours each.

Note: If your child does not have hearing loss, they will only participate in these activities on one day.

Sessions 5 and 6: You and your child will come to the VBWC on two days. One session will be on Saturday morning. The other session will be after school. In these visits, your child will complete several measures of literacy skills. Sessions 5 and 6 will last about 2 hours each.

Does my child have to do these activities? No, your child does not have to be in this study. You can say yes now but change your mind later. You and your child can drop out of the study at any time. Call or write to us if you want to drop out. It is possible that some children may feel bored, tired or frustrated during the sessions. Others might feel anxious about the activities. We will pay attention to how your child acts. We will offer him/her breaks and frequent praise. Your child may ask to stop at any time. There are no penalties for not participating. We may withdraw children from the study if they have certain diagnoses, such as autism or cognitive impairment. Or we may withdraw children if they are overly frustrated or anxious on more than one day. We will contact you before making any withdrawal decisions. If you withdraw, we will keep your child's data unless you request that we destroy it.

What are the benefits of this study and your participation? We cannot guarantee that you or your child will benefit from this study. The results may help us understand more about the effects of listening fatigue for children with hearing loss. The results may help guide the development of interventions. Your child may benefit from gaining experience in taking knowledge assessments. Receiving your child's test results may be helpful to your family. You may choose to share this information with your child's teacher.

Will my child receive anything for participating? Children will receive \$150 when they complete the cheek swabs. Children will receive an additional \$150 when they complete the rest of the study. If your child does not complete all parts of the study, he/she will not receive the additional \$150.

Will anyone know how my child responds? We will tell you how your child responds at your request. We will make every effort to keep your child's information confidential.

Date of Approval: 9/30/2013
Date of Expiration: 9/29/2014



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child's name. Codes will be made from your child's first initial and four letters from your child's last name. Some sessions will be audio recorded so we can check scoring of responses. The recordings will be stored on a password-protected server. A copy of audio CDs and assessment results will be stored in locked files in VBWC. Data will be entered into an electronic database. The database will be stored on a password-protected server. When the study is over, data will be kept in a file on a password-protected server. The data may be used in future studies.

Information from this study will not become a part of your child's school or medical records. Your information may be shared with Vanderbilt or the government, such as Vanderbilt University Institutional Review Board or Federal Government Office for Human Research Protections, if you or someone else is in danger or if we are required to do so by law.

What if I have questions? If you have any questions, please call The Listening and Learning Lab at Vanderbilt at 615-936-7498 or Sheila Lewis at 615-936-7525. Or you can email us at fatiguestudy@vanderbilt.edu. For additional information about giving consent or your rights as a participant in this study, please contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

What should I do? If you want your child to be in the study, fill in the information and sign below. An extra copy of this consent letter is included for you to keep.

STATEMENT BY PARENT ALLOWING CHILD TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date

Signature of child's parent or guardian

- I would like a copy of my child's test results.

- I agree to be contacted in the future about studies in the Vanderbilt Bill Wilkerson Center.

The researcher will complete this section.

Consent obtained by:

Date

Signature

Printed Name and Title



