Protection of Human Subjects

Risks to the subjects

Through Co-PI Allen's previous speech perception research, it has been established by the University of Illinois IRB committee that the risk to the subjects in this experiment is minimal. The most serious concern would be high levels of sound delivered over earphones. This possibility is easily avoided by hard-limiting the upper level. By its very nature, the upper levels of the laptop computers used in these experiments do not put out high levels of sound (max of 1 volt RMS). High levels of sound are not required for the experimental conditions, which are all presented in quiet. Furthermore, the sound level is monitored by a trained experimenter running each session.

Human subjects involvement and characteristics: The parameters of the human subject involvement is spelled out in some detail in the IRB forms. Specifically, all participation will be strictly voluntary and will follow written informed consent from children's parents/guardians and potential child subjects. Subjects and their families will be free to stop participating or withdraw at any time without penalty or prejudice to their relations with the University of Illinois or the Reading Group center. Participation will require approximately 19 sessions (3 assessment sessions, and two 8-block experimental sessions), each of which will be one hour in duration (broken into 10-min blocks of trials, with 5 min play breaks between blocks). The child's comfort with the experimental tasks will be monitored throughout a session.

The test signals will be played using the high quality earphones. Participants will be asked to adjust the level of signals that they hear over earphones so that it is at a "comfortable listening" level.

Potential risks: None are known.

Adequacy of protection against risks:

The upper levels of the sound are limited by the sound card in the laptop computer and by the type of earphones used. We instruct the subject that if they feel the sound is too loud, to stop the experiment and inform the person running the experiment. The same is true if the child becomes tired of the task.

Assessment batteries for reading, speech, language, hearing, and nonverbal cognition will be administered by clinically trained, speech-language pathologists, who hold Masters degrees in the field.

Recruitment and informed consent: Standard IRB procedures have been followed in Co-PI Allen's previous speech perception research and our preliminary studies for the proposed project, and will continue to be followed. The University of Illinois Beckman Institute and Dept. of Speech and Hearing Science and our collaborator, The Reading Group center, will be fully informed on the necessary approvals from the University IRB committee, as required. Written informed consent will be obtained from childrens parents/guardians and potential child subjects.

Protection against risk: The subjects are instructed to stop the experiment if they find the sounds too loud, and not to proceed. This is in the written instructions, and verbally explained to the subjects. All data collected (including original assessment data forms) will be identified only by an assigned name and subject number and kept in the locked laboratories of the PIs, in the Dept. of Speech and Hearing Science, and the Beckman Institute. The key linking the subject to her or his identification label will be destroyed at the end of the study.

Potential benefits of the proposed research to the subjects and others

There are several potential benefits: (a) results of the assessment battery may help the child's family understand the child's reading disability, (b) the experimental training condition may result in improved speech perception and possibly benefit the child's reading, (c) 20 concurrent reading lessons at The Reading Group will be funded by this research and may also result in reading improvement for the child, and (d) the control subjects will receive a small amount of remuneration ($10 per session, for 23 sessions).

Importance of the knowledge to be gained

If successful, it may be possible to help with reading intervention during the experiment, since we will be testing for this possibility. The knowledge gained from the study is intended to improve our understanding of aural sensory difficulties that may underlie poor phonemic awareness and, ultimately, reading disabilities.