Human Subjects

Oversight and protection of private information in accordance with HIPPA will be provided by the OHSU Institutional Review Board, which currently oversees the PART project Dr. Gallun runs at OHSU and the VA Portland Health Care System. For this pilot project, Dr. Bennett will be added as study personnel to the existing IRB at OHSU overseeing the NIH R01 and project amendments will be submitted to extend the current age range to include ages 5-19 years, add MESD as a testing site and acknowledge the additional funding. An example assent form is attached in the appendices, which will be updated once the project is approved. An example consent can be provided upon request.

Consent

Once a potential participant has been identified as meeting inclusion criteria, a member of the research team will first explain the nature of the study. The subject will be encouraged to ask any questions he or she might have, and the member of the research team will provide answers. After it is clear that the subject and parent/guardian understands the nature of the study, the research team member will emphasize that the subject is under no obligation to participate and will offer to answer questions about the study at any time during the subject's participation. If the subject agrees to participate in the study, he or she will be asked to sign the consent, assent and HIPAA forms, including a description of private health information to be collected and how such information will be used. A copy of the consent, assent and HIPPA authorization forms will be provided to the subject.

Risks to Subjects

This is a minimal risk study. The subjects will all be predominantly healthy participants with the potential exception of hearing loss. The only risks are those associated with routine audiological practice, such as boredom or fatigue. Staff will diligently monitor subjects to minimize any discomforts. All sound levels to be used in the studies fall below the Damage Risk Criteria established by OSHA for intensity-duration interaction. In the unlikely event of a breach of confidentiality, data about the subjects' hearing ability may be revealed.

Potential Benefits to Subjects

No benefit to individual volunteers will be received from participation on these studies beyond an up-to-date audiogram and a further understanding of their own hearing.

Remuneration

Subjects will be provided remuneration of $25 for participation. This rate is consistent with current practice at OHSU, and in the field of auditory research, generally. This amount compensates the participants for their time and effort and has not been found to be coercive, regardless of economic status of the participant. The full payment will be given during the visit,

provided the subject has at least begun the experimental testing. There will be no costs to subjects to participate in this study.

Handling of Data

No identifiable information will be included in data files. The data will be associated with a coded identifier, collected on a non-networked iPad, and moved for storage to a secure server or back-up location at OHSU and, if appropriate and available, at MESD. Trial-by-trial data including the stimulus characteristics of each trial and the subject's response are collected on the iPad and stored in encrypted data files that can only be accessed by connecting the iPad to a computer via a hardware connection and entering the correct password. De-identified and anonymized data will be aggregated and shared with the other investigators, clinicians, and educators, as well as in appropriate public repositories. Secure data transfer between the MESD and OHSU will be done electronically via the encrypted OHSU data site (Box.com) or physically via the iPads on which data were collected or via OHSU-encrypted portable hard drives.

Privacy, Confidentiality, and Data Security

Subject confidentially will be protected by using only identifiers assigned sequentially and containing no identifying information. Signed consent, assent and authorization forms, as well as the file linking the identifiers with participant names and contact information will be stored separately from the experimental data, so that families may be contacted at a future date. Any written or oral report or publication of the information obtained in this study will not contain the names of subjects or identifying information. All data records will be stored on computers or as hard copy in locked offices or laboratories. Experimental data will be collected and stored on iPads or experimenter computers with no identifiable subject information and will be backed up to the secure OHSU servers regularly. Data are stored in the laboratory and/or in the experimenter's offices, all of which are kept locked when no one is there.