The iPhone as an Appropriate Hearing Assistive Technology in the Classroom?

HUMAN SUBJECTS:

The proposed research will be approved by Montclair State University's Institutional Review Board prior to beginning data collection. The elements, design, procedures that are planned to provide adequate protection to human subjects are outlined here:

Recruitment: Participants primarily will be recruited in two ways: (1) the Montclair State University IRB-approved clinical audiology database will be searched to identify individuals who have indicated willingness to be contacted regarding future studies and (2) clinical audiologists at Hackensack University Medical Center will provide recruitment materials to patients who meet the criteria. Using the clinical audiologists rather than the applicant to recruit patients will avoid coercion due to a sense of obligation or fear that clinical care will be affected by the decision to participate or not. Other recruitment means will include sending advertisements to discussion boards/groups and word of mouth.

<u>Informed Assent/Consent:</u> Because teenagers will be recruited for participation, both assent and parent/guardian consent will be obtained for those participants < 18 years old, and a standard consent form will be obtained for participants 18 - 21 years old. The voluntary nature of participation will be explained, and participants will also be informed that they can stop at any point, even before completion of the procedures.

<u>Compensation:</u> Modest compensation will be provided to offset costs of time/travel for participation.

Risks: The possible risks associated with the proposed methods are typical of the risks associated with all clinical procedures, including standard clinical audiology appointments. The applicant who will be performing the procedures is informed about the proper approach as she is an AuD student. She has taken two courses in amplification and has had both on-site and off-site clinical placements, providing experience with both audiology evaluations and hearing-aid fitting.

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The research advisors are all licensed/certified audiologists. The primary advisor will supervise the experimental set-up and take responsibility that appropriate audiologic procedures are followed. All stimuli will be calibrated prior to seeing subjects to ensure safe presentation levels.

Protection of Privacy and Confidentiality of Data: The applicant and research team will keep participant information confidential. Personal, identifying information will be obtained from the subjects (e.g. date of birth, hearing sensitivity, etiology and progression of hearing loss, educational placement, current device use, etc.). To protect that information, each participant will be assigned a subject code, and data will be linked to the code rather than name. All electronic data will be stored on password protected computers housed within locked laboratories. Printed data will be stored in locked filing cabinets housed within locked laboratories.

The applicant and all research team members have completed and are up-to-date with the CITI human subjects certification. The following page is a letter from the research compliance officer at Montclair State University regarding Institutional Review.



Research Integrity and Compliance Institutional Review Board Academic Affairs Voice: 973.655.7781

March 29, 2018

Education Audiology Association Noel D. Matkin Awards

Re: Grant Application "The iPhone as an Appropriate Hearing Assistive Technology in the Classroom." Principal Investigator: Erin Roach

To Whom It May Concern:

We will review the IRB application for the above reference study, in accordance to our policies, once it has been submitted. The anticipated time window for IRB submission is: June-July 2018. Normally a PI will submit their IRB application after they receive the offer of an award. Our IRB is registered with the federal Office of Human Research Protections (OHRP), IORG #0003058. FWA #00005270

Respectfully,

Hila Berger

Digitally signed by Hila Berger DN: cn=Hila Berger, o=Montclair State University, ou=Compliance, email=bergerh@mail.montclair.edu, c=US

Hila Berger Director, Research Integrity and Compliance

cc: Rachel Scheperle, Assistant Professor (10M), Communication Sciences and Disorders