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TITLE: Enhanced Objective Measures for Evaluating Longitudinal Changes in Within-Subject Listening Difficulty

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CONTRACTING ORGANIZATION: Henry M. Jackson Foundation, Bethesda, MD

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6. AUTHOR(S)

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8. PERFORMING ORGANIZATION REPORT NUMBER

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14. ABSTRACT

Service members (SMs) often report experiencing hearing difficulties that far exceed what would be expected based on standard clinical auditory evaluations. The goal of this proposal is to develop better measures of speech-in-noise performance and listening effort that are reliably sensitive to the often subtle hearing difficulties that our SMs report. This will be especially important in future work that aims to track the benefits that are expected from a hearing restoration intervention. Aim 1 will develop a speech-in-noise test for a portable tablet or smartphone that can collect performance and response time data across multiple at-home sessions. Aim 2 will evaluate using a physiological measure (pupil dilation) to measure differences in listening effort between patients with hearing difficulties and controls. Aim 3 will investigate the use of commercially-available head-mounted displays (HMDs) that can measure pupillometry as a platform for implementing the take-home hearing tests developed under Aim 1. Participants will be SMs with hearing difficulties that exceed what would be predicted based on their hearing thresholds or healthy control participants. Some participants will perform the listening tests while using real or simulated low-gain hearing aids. Tests will include standard or modified clinical tests of speech-in-noise and other auditory abilities. Measures of interest will be changes in performance and reaction time within and across testing sessions, as well as pupillometry indicators of listening effort and fatigue/alertness. We intend for the results of this work to inform counseling, clinical decisions, and validation of treatments so that patients are provided the best hearing possible and to ensure Warfighter readiness for duty.

15. SUBJECT TERMS
None listed.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	18	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Service members (SMs) often report experiencing hearing difficulties that far exceed what would be expected based on standard clinical auditory evaluations. The goal of this proposal is to develop better measures of speech-in-noise performance and listening effort that are reliably sensitive to the often subtle hearing difficulties that our SMs report. This will be especially important in future work that aims to track the benefits that are expected from a hearing restoration intervention. Aim 1 will develop a speech-in-noise test for a portable tablet or smartphone that can collect performance and response time data across multiple at-home sessions. Aim 2 will evaluate using a physiological measure (pupil dilation) to measure differences in listening effort between patients with hearing difficulties and controls. Aim 3 will investigate the use of commercially-available head-mounted displays (HMDs) that can measure pupillometry as a platform for implementing the take-home hearing tests developed under Aim 1. Participants will be SMs with hearing difficulties that exceed what would be predicted based on their hearing thresholds or healthy control participants. Some participants will perform the listening tests while using real or simulated low-gain hearing aids. Tests will include standard or modified clinical tests of speech-in-noise and other auditory abilities. Measures of interest will be changes in performance and reaction time within and across testing sessions, as well as pupillometry indicators of listening effort and fatigue/alertness. We intend for the results of this work to inform counseling, clinical decisions, and validation of treatments so that patients are provided the best hearing possible and to ensure Warfighter readiness for duty.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

service members, hearing difficulties, speech-in-noise recognition, listening effort, low-gain hearing aids, at-home testing

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Status as of 12 Months After Contract (MAC)	Target Timeline (MAC)	Status (% Complete) or Completion Date
Specific Aim 1: Develop a speech-in-noise (SIN) test to collect performance and response time data across multiple at-home sessions. *Major Task 1: Improve our ability to obtain reliable and sensitive behavioral measures of performance on take-home, multi-session tests of auditory function in individuals with and without hearing difficulties that exceed what would be predicted based on audiometric thresholds.*		
Subtask 1 – Review and approval of protocol by local IRB and HRPO.	1-5	Approval by Walter Reed IRB; Have petitioned HRPO for waiver of single IRB requirement.
Subtask 2 – Design and develop tasks and infrastructure to implement take-home tablet measures (Site 1 is lead; Site 2 will consult)	1-6	Partial.
Modify and test existing tablet-based task presentation software for auditory functional tests to be conducted across multiple at-home sessions	1-5	Tasks in place; Need to be integrated into single application
Modify and test existing data analysis software	4-6	Not yet initiated
Subtask 3 – Collect data (n = 20 LGHA patients & 20 NH controls)	7-33	Not yet initiated.
Subtask 4 – Analyze and begin to publish and present results	12-36	Not yet initiated.
Specific Aim 2: Test the hypothesis that HD>HT individuals exhibit higher levels of listening effort than those who report fewer HDs but similar HTs. *Major Task 2: Identify measures of effort that are sensitive to differences between individuals with hearing difficulties with normal or near-normal hearing thresholds*		

Subtask 1 – Review and approval of protocol by local IRB and HRPO.	1-5	Main protocol complete: 08/04/23 WRNMMC site protocol in progress (75%)
Subtask 2 – Design and develop tasks and infrastructure to implement laboratory-based research study	1-6	In progress
Set up and test eye tracker and related equipment at both sites to ensure reliability of results across laboratories	1-6	In progress (80%)
Modify and test existing data analysis pipelines	5-6	In progress (80%)
Subtask 3 – Collect data (n = 25 HD>HT individuals & 25 NH controls)	7-24	Not yet initiated
Subtask 4 – Analyze and begin to publish and present results	25-36	Not yet initiated
Specific Aim 3: Compare the use of commercially available HMDs and research-grade eye tracking systems to measure listening effort. *Major Task 3: Determine whether head-mounted displays can provide comparable sensitivity to differences in effort as high-end research systems across challenging listening conditions*		
Subtask 1 – Review and approval of protocol by local IRB and HRPO.	1-5	Main protocol complete: 08/04/23
Subtask 2 – Design and develop tasks and infrastructure to implement laboratory-based research study (Site 2 is lead, Site 1 will consult)	1-6	In progress
Set up and test head mounted display eye tracker and related equipment	1-6	In progress (80%)
Modify and test existing data analysis pipelines	5-6	In progress (80%)
Subtask 3 – Collect data (n = 25 NH controls [from Aim 2])	7-24	Not yet initiated

Subtask 4 – Analyze and begin to publish and present results	25-36	Not yet initiated

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Aim 1:
Aim 1 builds on an existing software platform based on TabSINT software that has been used in previous take-home studies with patients. Speech-in-noise stimuli using the Modified Rhyme Test have been recorded through low-gain hearing aids and have been collected using a KEMAR acoustic manikin in a simulated cafeteria environment. Pilot listening has been accomplished using these stimuli. We have also obtained regulatory approval from the Walter Reed IRB on a research protocol to begin data collection, but we are waiting for OHRO approval. OHRO has requested us to submit a request for a waiver of single IRB review to allow us to use this protocol to begin data collection.

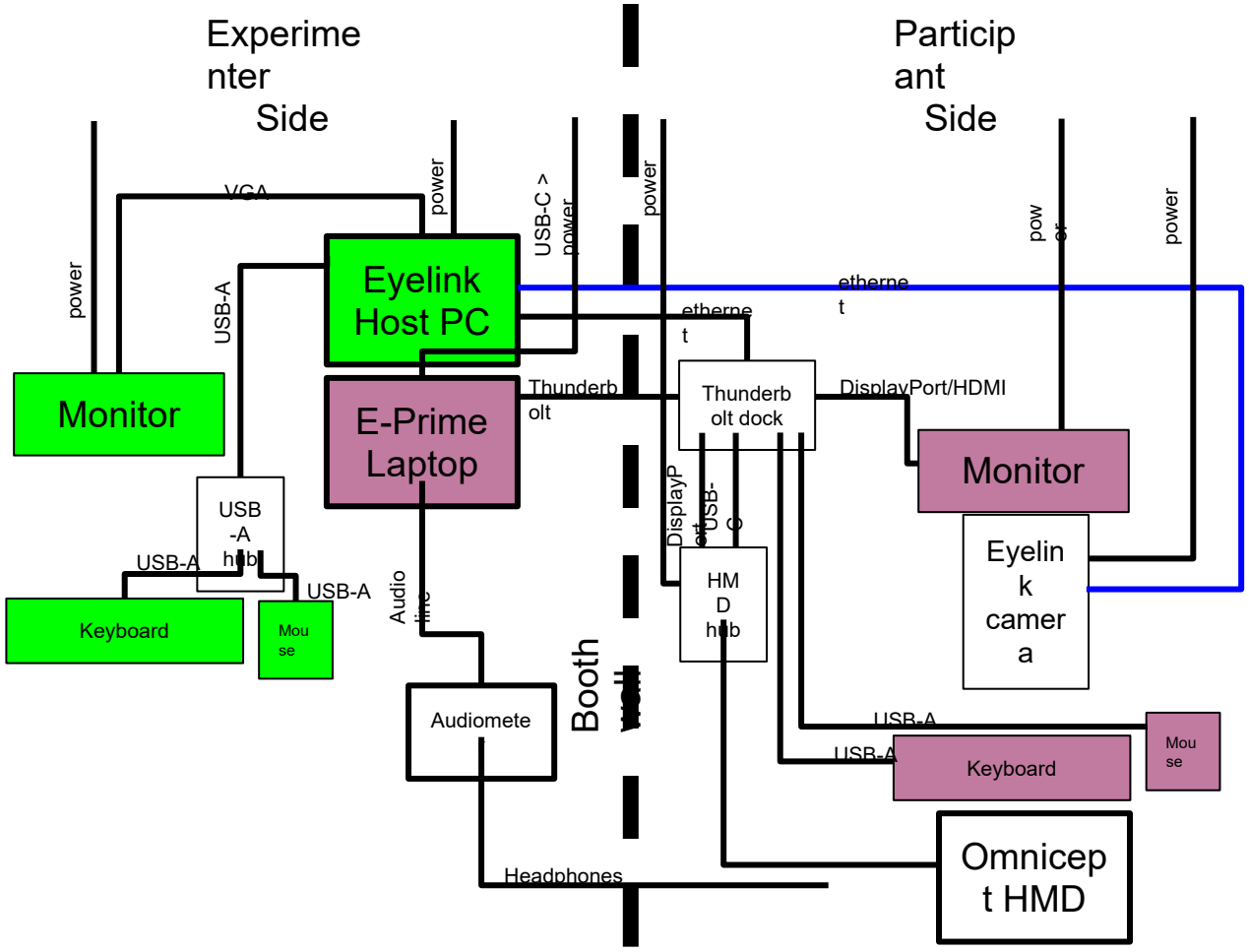
Aims 2 and 3:
Task 2.1 and 3.1 (review and approval of protocol by local IRB and OHRO) have been completed for the main protocol that will cover Aims 2 and 3 at the University at Buffalo. A full protocol for the WRNMMC site had also been submitted (03/24/23) to the local WRNMMC IRB. Upon learning that OHRO would require a single IRB review, we sought out and obtained an IAIR agreement, signed by both UB and WRNMMC, to allow for reliance on UB's IRB. An amendment to add WRNMMC as a site to the already approved protocol is expected to be submitted in November.

To ensure data collection is not significantly hindered as a result of longer-than-expected review processes, the WRNMMC site protocol will include a HIPAA Preparatory to Research Provision, which will allow study members to identify potential participants from clinical databases (Genesis, Audbase). Additionally, research support staff have begun training on participant recruitment methods and standards of practice from the audiology clinic at WRNMMC. We are working closely with the clinical audiologist supporting this project to set up a mechanism for rapidly identifying potential research participants. At UB, students have been trained to collect data on the research-grade eye tracker.

Progress has also been made on identifying, acquiring, setting up, and testing equipment for this project at both sites. This equipment includes: laptops to run pupillometry tasks; head mounted displays; peripheral hardware; Eyelink 1000 Plus desktop mounted eye tracker; as well as the

laboratory space and audiology booths to perform the testing.

A diagram of the setup of the laptop, peripherals, and two eye trackers (research grade vs. head mounted display) is shown below:



In terms of progress on study procedures, our team has finalized the tasks and conditions of our experiments and surveys. The majority of these are already programmed and are being tested prior to our ability to start data collection. Software is under development for storing trial level pupillometry data along with behavioral data in the TabSINT tablet testing architecture. The usability of the custom HMD data collection application has been enhanced.

In preparation for data collection and analysis, we have also been working to analyze the quality and precision of pupillometry data collected from a HMD for a separate project to inform the development of data analysis pipelines for the current protocol. We have developed cross-site pipelines for sharing, pre-processing, and analyzing data. These preparations will ensure that IRB-related delays do not negatively impact our ability to collect and analyze data once approval is obtained at all sites.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Aim 1:
In the next reporting period, we plan to finalize OHRO approval of our WRNMMC protocol that applies only to Aim 1. Thus, we will make significant progress on data collection with the goal of meeting our original recruitment estimates.

Aims 2 and 3:
Over the next reporting period, we plan to obtain IRB and OHRO approval at both sites and thus make significant progress on data collection, aiming to meet our original goal of completing data collection (25 at WRNMMC and 25 in two sessions each at UB).

4. IMPACT: D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Significant progress is being made on the integration of tablet-based behavioral and eye-tracking data collection via the TabSINT architecture. Once implemented and fully tested, we anticipate that this will provide a platform for researchers to collect these data streams across many different domains of study. Furthermore, this integration is expected to have clinical utility, as the TabSINT platform is already being used to collect standard audiometric measures in clinics. The ability to unobtrusively collect pupillometry data on the same system at the same time has the potential lead to advances in our ability to understand changes in performance along with changes in physiological measures of mental effort and fatigue.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

The primary delay with respect to our timeline is related to obtaining OHRO approval. With respect to Aim 1, a protocol was submitted and approved by the local WRNMMC IRB. It was submitted to OHRO and we are working with them to ensure we address their questions and feedback. With respect to Aims 2 and 3, originally, two protocols were submitted separately to UB's IRB and to WRNMMC's IRB to reflect the different sites and populations studied. However, OHRO identified that a single IRB review was needed. We initiated an IAIR agreement for WRNMMC to rely on UB's IRB, which took three months to be signed. Once obtained, OHRO approved UB's protocol with the understanding that WRNMMC's site approval would be included as an amendment within the single IRB protocol at UB. Data collection is approved to begin at UB, and the lab space is actively being configured in preparation for enrollment. Administrative review of the site protocol at WRNMMC is anticipated to be submitted in November, with UB approval of the amendment soon following. OHRO approval will be required to review this amendment before data collection can begin at WRNMMC.

As described in the accomplishments section, we have been making progress on our recruitment and data analysis pipelines in preparation for being able to begin data collection. In this way, we believe that these administrative hurdles will not impede our ability to collect the data as stated in the statement of work.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page*

numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Nothing to report.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report.

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:
Name: *Mary Smith*
Project Role: *Graduate Student*
Researcher Identifier (e.g. ORCID ID): *1234567*
Nearest person month worked: *5*
Contribution to Project: *Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support: *The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Name	Douglas S. Brungart, Ph.D.
Project Role	PI
Research Identifier	
Nearest person month worked	.6
Contribution to Project	Dr. Brungart has provided administrative oversight for the project and directed the development of the research protocol and implementation.
Funding Support	Federal civilian employee
Name	Stefanie E. Kuchinsky, Ph.D.
Project Role	co-I
Research Identifier	ORCID: 0000-0001-9320-486X
Nearest person month worked	1.2
Contribution to Project	Dr. Kuchinsky has led WRNMMC efforts related to human subjects approval, study design for the pupillometry studies, and annual reporting.
Funding Support	Federal civilian employee
Name	Ian Phillips, Ph.D.
Project Role	Research Scientist
Research Identifier	
Nearest person month worked	1.2
Contribution to Project	Dr. Phillips has contributed to the development, implementation, and testing of eye tracking hardware and software and survey measures.
Funding Support	N/A
Name	Jacob Lefler

Project Role	Research Engineer
Research Identifier	
Nearest person month worked	1.2
Contribution to Project	Mr. Lefler has led the efforts to select, implement, and test the necessary hardware and software to support data collection efforts for the pupillometry aims of the study.
Funding Support	N/A
Name	Kim Jenkins, AuD
Project Role	Audiologist
Research Identifier	
Nearest person month worked	1
Contribution to Project	Dr. Jenkins is a clinical audiologist at WRNMMC who sees the SM patient population of focus in this study – SMs with hearing difficulties that exceed those predicted by their hearing thresholds. She has been helping to develop recruitment procedures that will eventually be used to efficiently identify potential participants.
Funding Support	Federal civilian employee

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)
- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name: University at Buffalo Location of Organization: Buffalo, NY Partner's contribution to the project: Collaboration The University at Buffalo is the project sub-awardee and directs the studies collecting normative data on healthy younger adults.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*