**SUMMARY STATEMENT**

**PROGRAM CONTACT:** [redacted]

**( Privileged Communication )**

***Release Date:*** **03/23/2017**
***Revised Date:***

***Application Number:*** **1 R21 DC015832-01A1**

**Principal Investigator**

**WALKER, ELIZABETH A.**

**Applicant Organization: UNIVERSITY OF IOWA**

***Review Group:*** **CDRC**
**Communication Disorders Review Committee**

***Meeting Date:*** **02/09/2017**
***Council:*** **MAY 2017**
***Requested Start:*** **07/01/2017**

***RFA/PA:*** **PAR16-057**
***PCC:*** **HR05**

***Project Title:*** **Mechanisms of Listening Effort in School Age Children who are Hard of Hearing**

***SRG Action:*** **Impact Score:28**
***Next Steps:*** **Visit https://grants.nih.gov/grants/next_steps.htm**
**Human Subjects:** **30-Human subjects involved - Certified, no SRG concerns**
**Animal Subjects:** **10-No live vertebrate animals involved for competing appl.**
**Gender:** **1A-Both genders, scientifically acceptable**
**Minority:** **1A-Minorities and non-minorities, scientifically acceptable**
**Children:** **2A-Only Children, scientifically acceptable**
**Clinical Research - not NIH-defined Phase III Trial**

| Project Year | Direct Costs Requested | Estimated Total Cost |
|---|---|---|
| 1 | [redacted] | [redacted] |
| 2 | | |
| 3 | | |
| TOTAL | [redacted] | [redacted] |

**ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.**

**1R21DC015832-01A1 Walker, Elizabeth**

**RESUME AND SUMMARY OF DISCUSSION:** This resubmitted application for an NIDCD Early Career Research (ECR) Award (R21) seeks three years of support for Dr. Walker to study the underlying mechanisms responsible for increased listening effort in school-aged children with hearing loss. The promising PI is very well trained, highly productive, and has a unique level of expertise in clinical and basic research. The co-investigator team is strong. This resubmitted application is clearly written, the aims are well defined with testable hypotheses and an underlying theoretical structure. This proposal will not only quantify the degree of listening effort expended by children with varying degrees of hearing loss as well as the type and the quality of the audiological intervention, but will also examine higher level cognitive processes including working memory and receptive vocabulary. Further, this proposal aims to investigate speech understanding in noise, visual-motor reaction time, as well as both combined in a dual-task paradigm in a group of children with permanent hearing loss as well as age-matched peers with normal hearing. The proposal has high theoretical, clinical and educational significance. Weaknesses of this application include the lack of a global language assessment, the lack of control for technology aimed at improving signal-to-noise ratio, and that the rapid development in neurocognitive processing for the proposed age range being studied is not adequately considered with the cross sectional study design.

**DESCRIPTION (provided by applicant):** Many children with mild to severe hearing loss are identified and receive early intervention at very young ages. Even with this early intervention, however, children who are hard of hearing (CHH) experience challenges with communication due to reduced access to the auditory signal. These challenges are further compounded in school because CHH have increased difficulty perceiving speech in adverse acoustic conditions and most listening conditions are characterized by poor acoustics. When listening in adverse conditions, CHH must exert additional cognitive resources compared to children with normal hearing (CNH) in order to perceive an incoming message. Consequently, they have fewer cognitive resources available to perform additional tasks and must expend increased listening effort. Listening effort requires the coordination of low-level, bottom-up processes, and higher-level, top-down processes. There is a lack of evidence regarding the interplay between auditory access and higher-level cognitive skills in influencing individual differences in listening effort for CHH. This knowledge gap hinders the understanding of the underlying mechanisms that drive listening effort in children with hearing loss, which in turn, limits the ability to develop evidence-based interventions for this population. The current proposal seeks to determine the factors that underlie increased listening effort in school-age CHH. This proposal is based on a limited resources capacity theory, which posits that listeners require additional cognitive resources to maintain optimal listening performance during adverse acoustic conditions, and this demand on resources results in a decline in performance on secondary tasks. Specifically, the current proposal tests the hypothesis that top-down processing, quantified by working memory and linguistic skills, is associated with listening effort in school-age CHH, and this relationship is moderated by bottom-up processing, measured via aided audibility. Two specific aims are proposed to test this hypothesis: Aim 1. To determine the effect of higher-level cognitive-linguistic skills on listening effort in school-age children who are hard of hearing, and to evaluate the extent to which auditory access influences the relationship between cognitive-linguistic skills and listening effort. Aim 2. To identify the effects of hearing aid use and background noise on listening effort in children who are hard of hearing. In Aim 1, working memory capacity, receptive vocabulary, and aided speech audibility will be used to predict listening effort in varying levels of background noise. In Aim 2, listening effort for CHH will be evaluated in aided and unaided conditions, in quiet and in background noise. In both aims, different dimensions of listening effort will be captured, including reaction time, self-report measures, and speech recognition performance. The data

generated from this proposal will inform theoretical models regarding the integration of low-level, acoustic-phonetic input and higher-level, cognitive-linguistic processes involved in listening, using a mechanistic approach to examine listening effort. The proposed study will also provide empirical evidence for the development of effective interventions for children with hearing loss, in both classroom and social settings.

**PUBLIC HEALTH RELEVANCE**: The purpose of this research proposal is to identify the underlying mechanisms that influence listening effort in degraded acoustic environments with school-age children who have mild to severe hearing loss. The proposed research is relevant to public health because it will provide important insights into how children manage listening demands in complex auditory environments. This project is highly related to the NIH's mission because the data will guide evidence-based practice and policy for the clinical and educational management of children who are hard of hearing.

**CRITIQUES:** The written critiques of individual reviewers are provided in essentially unedited form below. These critiques were prepared prior to the meeting and may not have been revised afterwards. The "RESUME AND SUMMARY OF DISCUSSION" above summarizes the final opinions of the committee.

**CRITIQUE 1:**

Significance: 2
Investigator(s): 1
Innovation: 2
Approach: 4
Environment: 1

**Overall Impact:** The primary aim of this proposal is to identify the underlying neurocognitive mechanisms driving increased listening effort in children with hearing loss. The applicant will investigate speech understanding in noise, visual-motor reaction time, as well as both combined in a dual-task paradigm in children with various degrees of permanent hearing loss as well as age-matched peers with normal hearing. Primary variables of interest in the analysis include degree of hearing loss, aided SII, HA wear time, receptive vocabulary, and working memory. If successful, these data could help the PI and her research team identify those mechanisms that may be malleable thereby allowing for the development of an intervention strategy to help reduce listening effort in children with hearing loss. This application is an excellent example of good grantsmanship, it is well written and easy to read. The aims were well defined with testable hypotheses and an underlying theoretical structure. The primary concerns regarding the application are in the approach and include the lack of detail regarding the chosen variables, underlying neurocognitive development, functional outcomes, and potentially relevant issues related to everyday listening conditions for the children with hearing loss.

**1. Significance:**
**Strengths**

- Children with hearing loss exhibit significantly greater listening effort which holds potential to negatively impact academic success, language development, as well as a number of additional higher level cognitive processes. Thus, this proposal holds high theoretical, clinical, and educational significance.
- Given how little we understand about listening effort in children, this proposal will fill a gap in the knowledge base for this important area.

**Weaknesses**

- None noted by the reviewer

**2. Investigator(s):**
**Strengths**

- The PI is a highly promising, early stage investigator with a proven record of publication in high-impact, peer-reviewed journals (24 peer-reviewed publications, 6 as first author).
- The PI is dually certified in SLP and audiology. This provides her with extensive clinical expertise to apply her scientific outcomes with a focus on clinical application.
- The PI is a co-I on various large-scale NIH-funded projects.
- [redacted], a biostatistician, is listed as co-I and will thus be instrumental in carrying out the statistical analyses.
- [redacted] is an otologist and hearing scientist with extensive experience in hearing aid research and ecological assessment of auditory outcomes. His input as a consultant will be valuable to the project.
- [redacted], an expert in auditory cognitive science, is a valuable consultant to the project.

**Weaknesses**

- None noted by the reviewer

**3. Innovation:**
**Strengths**

- The proposed experiments will generate entirely new data in this research space thereby filling a gap in the knowledge base.
- This will be one of the first studies investigating subjective reports of listening effort in children with and without hearing loss.

**Weaknesses**

- Lack of validation for the subjective scale of listening effort in this population.

**4. Approach:**
**Strengths**

- Hypothesis-driven proposal, grounded in neurocognitive theory of attention capacity
- The PI has demonstrated feasibility with preliminary data collected for 9 pediatric participants
- The PI has access to an established cohort of research participants from the OCHL study.
- The use of individual and dual-task paradigms as well as a subjective measure of listening effort adds strength and rigor to the experimental design.

**Weaknesses**

- Little-to-no information is provided on the underlying reasoning for investigating receptive vocabulary alone in lieu of, or in addition to a measure of total language. This is especially problematic given that the underlying theory driving this aim is a model based on ease of language understanding which is not based solely on vocabulary.
- Working memory rapidly develops over the age range of the children in the current study—an issue given the cross-sectional nature of the proposed project. How might that impact the overall interpretation of the data?
- What are the consequences of increased listening effort in the current study? It's unclear whether the PI will investigate whether the child experiences greater difficulty in academics, social situations, overall quality of life, etc. Without an ability to tie this into a functional, consequential outcome, it is unclear that the proposed experiments will hold any promise for clinical or educational relevance.
- Does it matter whether the children are using remote microphone technology in the classroom? Might this impact a child's "neurocognitive baseline" for listening effort –particularly in conditions where the child is not using this technology. This would undoubtedly impact real-life listening effort, though would not be reflected in the data without adding a clinical manipulation.

**5. Environment:**
**Strengths**

- The environment at the University of Iowa is ideal
- The resources available to the research team are exceptional—especially having access to the participant population from the OCHL study.

**Weaknesses**

- None noted by the reviewer

**Protections for Human Subjects:** Acceptable Risks and/or Adequate Protections

- acceptable plan for the protection of human subjects

**Inclusion of Women, Minorities and Children:**

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 18: Including ages <18; justified scientifically
- Adequate justification for the inclusion of children < 18 years of equal gender distribution and racial and ethnic composition.

**Vertebrate Animals:** Not Applicable

**Biohazards:** Not Applicable

**Resubmission:**

- The applicant has done a nice job of addressing the majority of the concerns raised in the previous round.

**Select Agents:** Not Applicable

**Resource Sharing Plans:** Acceptable

- The PI thoroughly outlined plans for data collection, analysis, and data interpretation. Further she provided considerable detail regarding plans for dissemination of data including making the deidentified dataset available via data enclave

**Budget and Period of Support:** Recommend as Requested

- Budget is appropriate and thoroughly described

**CRITIQUE 2:**

Significance: 2
Investigator(s): 2
Innovation: 4
Approach: 3
Environment: 1

**Overall Impact:** The proposal is to study the relationship between cognition and listening effort in children with hearing loss. The questions are asked using the ever more popular dual task paradigm. The PI points out that while we have learned much about the dual task paradigm and can glean information about top down influences on speech perception, little is known in this domain in children with hearing loss. The proposed work is likely to add to our knowledge about speech/language

processing in children with hearing loss. The results might also provide strong evidence regarding the efficacy of hearing aids in children with hearing loss. One might argue that this evidence is unnecessary at this point, but data seems to suggest parents and families are not fully convinced about the benefits of consistently using hearing aids. The PI has nicely addressed concerns from the previous review. This reviewer has a couple of lingering concerns that are mentioned in the approach subsection but they should be easy to address.

**1. Significance:**
**Strengths**

- The need for deeper understanding of speech/language processing in children in general and children with hearing loss in particular is an important area of investigation.
- To emphasize significance, one might point to the funding status of the EHDI bill. Data such as those obtained here will support the importance of early detection of, and intervention for, hearing loss.
- Will support hearing aids as a treatment for hearing loss.

**Weaknesses**

- It may be the case that results such as these will have to be augmented with more physiological measures to truly understand the interplay between top down and bottom up processes involved in speech/language processing.

**2. Investigator(s):**
**Strengths**

- The PI is trained by some of the leading figures in the areas of pediatric hearing and cochlear implants.
- She has an extensive record of publications and participation in grants.
- The research she has and is participating in is very pertinent to her proposed work.

**Weaknesses**

- The PI's role in much of the previous work is unclear; however, with this proposal, the PI is establishing her line of independent work in listening effort.

**3. Innovation:**
**Strengths**

- The innovation is in the use of well-established methods in children with hearing loss.
- Whether innovative or not, the direct examination of the influence of amplification on listening effort is important.

**Weaknesses**

- The methods are not particularly innovative; however, this is not a weakness as appropriate methods are being used.

**4. Approach:**
**Strengths**

- The PI uses familiar methods, familiar not only to the field but also to the PI herself.
- The PI shows flexibility in her approach. For example, she indicates her willingness to change her protocol based on the indication that children with hearing loss may be running into the performance floor when the auditory stimuli are presented at an SNR of -5 dB.

**Weaknesses**

- Is the presentation of the visual stimulus anywhere in the second half of the sentence without peril? In other words, could the visual stimulus have a different effect on effort or accuracy when presented in close proximity to the end of the sentence? This is pure speculation, but this reviewer is wondering if the cognitive task changes at some arbitrary time point near the end of

the sentence presentation. The PI will have the data to ask whether this is true or not by simply plotting the presentation instant from the end of the auditory signal as a function of performance.

**5. Environment:**
**Strengths**

- The involvement of the collaborators adds valuable expertise.
- It is also clear that the PI will continue to receive support from her current collaborators who are not explicitly listed on the grant.
- The project can use the scaffolding built for the larger multi-center projects that the PI participates in.
- This is almost the perfect environment to conduct the proposed work.

**Weaknesses**

- None noted by the reviewer

**Protections for Human Subjects:** Acceptable Risks and/or Adequate Protections

- Commonly used methods proposed and safeguards in place.

**Inclusion of Women, Minorities and Children:**

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 18: Including ages <18; justified scientifically

**Vertebrate Animals:** Not Applicable

**Biohazards:** Not Applicable

**Resubmission:**

- The PI has done a commendable job responding to the previous reviews.

**Select Agents:** Not Applicable

**Resource Sharing Plans:** Acceptable

**Authentication of Key Biological and/or Chemical Resources:** Not Applicable

**Budget and Period of Support:** Recommend as Requested

**CRITIQUE 3:**

Significance: 1
Investigator(s): 1
Innovation: 2
Approach: 2
Environment: 1

**Overall Impact:** The purpose of this application is to study factors relating to listening effort among children who are hard of hearing (CHH). Listening effort is understudied in this population, so the proposal will fill an important gap in the literature. Systematically examining the relation between listening effort and other child related factors such as cognition and auditory access (hearing aid use)

and auditory environment could yield new insights into variable outcomes and individual differences and also ultimately inform intervention.

**1. Significance:**
**Strengths**

- The background provided a compelling rationale for studying cognitive factors as these relate to listening effort in children with hearing loss.
- The potential significance of listening effort in this population was well developed and grounded in the literature.

**Weaknesses**

- None noted by the reviewer

**2. Investigator(s):**
**Strengths**

- Dr. Elizabeth Walker is an Assistant Professor at U of Iowa. She received her PhD from Iowa in 2010, and completed substantial research experience both at Iowa (as a co-investigator on other grants of well-established researchers) and Indiana (while working as a research associate under Drs. Pisoni and Kirk). She is dual certified in speech and audiology and has considerable experience evaluating children. She already has 8 peer reviewed publications as 1st author and 8 as 2nd author in related areas of pediatric cochlear implants and children who are hard of hearing.
- Dr. Walker is well qualified to complete the proposed research.

**Weaknesses**

- None noted by the reviewer

**3. Innovation:**
**Strengths**

- There is strong innovation: both in terms of examining listening effort on aided and unaided conditions and combining listening effort with measures of aided audibility and cognitive-linguistic skills in the population.

**Weaknesses**

- None noted by the reviewer

**4. Approach:**
**Strengths**

- The project applies a reasoned theoretical model including measures of auditory factors and cognitive-linguistic skills as predictors of listening effort in CHH.
- The proposed research is clearly hypothesis driven and the use of appropriate measures (vocabulary, working memory, aided audibility) are strengths.
- Approaching the research questions with a combination of objective and subjective measures using a within subjects design will provide insight about the relationships between self-report judgments and cognitive-behavioral measures of listening effort.

**Weaknesses**

- One goal of the proposed research is to consider/model listening effort in noise. The approach would be strengthened if the functional/environmental correlates of noise were examined.
- The proposal would be strengthened if the role of language ability, especially comprehension beyond vocabulary were explored in more detail.

**5. Environment:**
**Strengths**

- The environment at the University of Iowa is outstanding

**Weaknesses**
- None noted by the reviewer

**Protections for Human Subjects:** Acceptable Risks and/or Adequate Protections
- No concerns

**Inclusion of Women, Minorities and Children:**
- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 18: Including ages <18; justified scientifically
- Minority recruitment should be better described

**Vertebrate Animals:** Not Applicable

**Biohazards:** Not Applicable

**Resubmission:**
- The proposal was responsive to previous reviewer comments

**Select Agents:** Not Applicable

**Resource Sharing Plans:** Acceptable

**Authentication of Key Biological and/or Chemical Resources:** Not Applicable

**Budget and Period of Support:** Recommend as Requested

**THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:**

**PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE**
Risks are minimal and appropriate protections are in place.

**INCLUSION OF WOMEN PLAN: ACCEPTABLE**
Equal number of boys and girls will be enrolled in the study. A statement about the prevalence of hearing loss according to sex/gender would have been helpful.

**INCLUSION OF MINORITIES PLAN: ACCEPTABLE**
The percentages of minorities enrolled are comparable to the state estimates. A statement about the prevalence of hearing loss among children of different race/ethnicity would have been helpful.

**INCLUSION OF CHILDREN PLAN: ACCEPTABLE**
Participants will be children ages 8-12, including children with normal hearing and children who are hard of hearing. This is scientifically justified.

**VERTEBRATE ANIMAL: Not Applicable (No Vertebrate Animals)**

**BIOHAZARD COMMENT: Not Applicable (No biohazards)**

**SELECT AGENTS: Not Applicable (No Select Agents)**

**SHARING RESEARCH DATA: Acceptable**

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.**

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Footnotes for 1 R21 DC015832-01A1; PI Name: Walker, Elizabeth A.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER
Communication Disorders Review Committee

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

CDRC
02/09/2017 - 02/10/2017

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. All questions should be directed to the Scientific Review Officer in charge of the study section. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-14-073 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html and NOT-OD-15-106 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html, including removal of the application from immediate review.

CHAIRPERSON(S)

MEMBERS

[redacted]

SCIENTIFIC REVIEW OFFICER

[redacted]

* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.