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TITLE: Identifying the Sources of Degraded Speech-in-Noise Understanding and Individualized Therapeutic Options

PRINCIPAL INVESTIGATOR: Inyong Choi, Ph.D.

CONTRACTING ORGANIZATION: University of Iowa

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14. ABSTRACT This project will identify the peripheral and central factors that predict the variance of speech-in-noise (SiN) understanding ability among normal hearing listeners. To achieve this goal, in Aim 1, neural substrates of all the key stages along the proposed SiN processing model will be characterized through within-subject design experiments of human electrophysiology. In Aim 2, a correlational study, we will characterize a hierarchical regression model that adopts the measures of auditory neural processes as independent variables and electrophysiological responses and behavioral performance during phonological and lexical processing as dependent variables. Finally, Aim 3 will seek an optimal, clinically applicable set of test batteries and measures that identifies 1) the sources of degraded speech-in-noise understanding and 2) the most effective, individualized therapeutic options.					
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1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Even among young "normal hearing" people, there is great variation in the ability to understand speech in noisy real-world settings. However, current audiology practice does not have the methods to diagnose and treat speech-in-noise (SiN) problems in normal hearing listeners. This project will identify the peripheral and central factors that predict the variance of SiN understanding ability among normal hearing listeners. To achieve this goal, in Aim 1, neural substrates of all the key stages along the proposed SiN processing model will be characterized through within-subject design experiments of human electrophysiology. In Aim 2, our correlational study will characterize a hierarchical regression model that adopts the measures of peripheral encoding, auditory grouping, and selective attention processes as independent variables, cortical responses during speech unmasking as a mediator, and electrophysiological responses and behavioral performance during phonological and lexical processing as dependent variables. Finally, Aim 3 will seek an optimal, clinically applicable set of test batteries and measures that identifies 1) the sources of degraded speech-in-noise understanding and 2) the most effective, individualized therapeutic options. This study will characterize several key neural processes required for successful speech understanding in social settings, and will promote our understanding of how peripheral and central processing deteriorates in listeners with degraded ability.

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

Speech in noise, peripheral auditory encoding, auditory grouping, auditory selective attention, phonological processing, lexical processing, electroencephalography (EEG), electrocorticography (ECoG)

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.

This is the third-year annual report. By the third year, this project aimed to complete the following studies:

1. Aim 1: Within-subject study to characterize neural mechanisms of auditory grouping: 1) With scalp EEG in normal subjects and 2) with electrocorticography (ECoG) in epilepsy patients.
2. Aim 1: Within-subject study to characterize neural mechanisms of selective attention: 1) With scalp EEG in normal subjects and 2) with ECoG in epilepsy patients.
3. Aim 1: Within-subject study to investigate the effect of neurofeedback attention training on speech-in-noise perception: 1) With scalp EEG in normal subjects and 2) with ECoG in epilepsy patients.

4. Aim 2: Correlational study to characterize the relationship between the fidelity of peripheral auditory encoding [measured by medial olivo-cochlear reflex (MOCR), middle ear muscle reflex (MEMR), and auditory brainstem responses (ABR)] and speech-in-noise performance.
5. Aim 2: Correlational study to characterize the relationship between auditory grouping ability and speech-in-noise performance
6. Aim 2: Correlational study to characterize the relationship between selective attention ability and speech-in-noise performance
7. Aim 3: Finding the optimal layout of EEG electrodes for the assessment of neural processing for speech-in-noise
8. Aim 3: Comparing signal qualities between dry and wet EEG electrodes

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.

1) Major activities

We have conducted within-subject studies from 110 EEG subjects and 6 ECoG subjects, which nearly completes the data collection goal at the end of Year 3 for the EEG portion. Currently we are at the 87.9% point of the total data collection goal.

Based on our interim results from the data we have collected so far, we submitted four manuscripts to peer-reviewed journals all of which were accepted or published. Key outcomes from the data analysis and the list of publications are described in the following sub-sections (including Section 3: Significant results and key outcomes).

2) Specific objectives

Objectives of the Aims 1 and 2 within- and across-subject studies were to identify neural markers of speech-in-noise variance in normal hearing listeners. The object of Aim 3 was finding efficient scalp EEG electrode layouts that effectively captures neural predictors of speech-in-noise ability.

3) Significant results and key outcomes

Our key outcome is that we proved the concept of neurofeedback training that improves auditory selective attention. Perceptual training facilitates neural plasticity to improve listeners' auditory and cognitive abilities by having a trainee engaged actively with a challenging sound that exploits perceptual or cognitive resources. Active engagement in training and repeated exposure to novel sound may induce anatomical and physiological changes that occur across existing neural pathways and even includes the budding of new connections, resulting in better auditory or

cognitive function. Indeed, recent studies showed that training on extracting low-intensity signals from background noise and sustaining attention to the signals resulted in enhanced SiN performance.

Theories of learning claim that the target of training is manipulated by rewards. The determination of feedback (i.e., reward or punishment) must be based on the target training component. Thus, to enhance attentional modulation of cortical responses, a training paradigm should provide feedback based on the strength of attentional modulation. While traditional perceptual training provides behavioral feedback at the end of a trial, we instead consider providing neurofeedback using brain-computer interfaces. The goal of neurofeedback training is that if subjects learn how to adapt neural activity consciously, it may result in specific patterns in neural activity that reach the pre-defined threshold level, followed by a reward to the subjects.

Our neurofeedback training paradigm aims to "explicitly" enhance the attentional modulation of cortical auditory evoked responses. Twenty subjects (i.e., ten in each of the Experimental and Placebo groups) participated in the pilot training program of 4-week training. See Figure 1A for the trial structure of the pilot training experiment. Both Experimental and Placebo Groups listened to two concurrent speech streams: A female voice repeating "Up" five times and a male voice repeating "Down" four times. The female voice ("Up") was played from the loudspeaker on the left (-45° azimuth), while the male voice was played from the right ($+45^\circ$). No physical overlap between competing speech streams in time and location was intended to maximize stream segregation. Before the sound begins, subjects were instructed to attend to one of those streams by a visual cue saying "Target: Up" or "Target: Down". 64-channel EEG was recorded throughout the experiment. Right after the sound, auditory selective attention was decoded from single-trial EEG signals based on the template-matching classification method. That means the single-trial EEG signal was compared to pre-defined "ideal" EEG waveforms (i.e., "Templates"). One template (i.e., "Template: Up") resembled the sound waveform of the "Up" stream (i.e., red waveforms in Figure 1A). The other template (i.e., "Template: Down") resembled the sound waveform of the "Down" stream (i.e., blue waveforms in Figure 1A). For example, if the single-trial EEG waveform shows greater similarity (i.e., correlation) with the "Template: Down" than the "Template: Up," the EEG decoder determines that "Down" was attended while "Up" was ignored. Only the Experimental Group subjects received neurofeedback (i.e., the fixation cross on the computer screen moves upward if the EEG decoder determines that the "up" stream was attended; it moves down if the EEG decoder determines that "down" was attended). The Control Group underwent a similar selective attention training but did not receive the neurofeedback. Since the accuracy of decoding attention from single-trial EEG signals reflects the strength of attentional modulation on cortical auditory evoked responses, providing the result of EEG-based attention decoding as neurofeedback was expected to reinforce trainees' attentional modulation of cortical responses.

During the last 4th week training, compared to the first week, Experimental Group participants exhibited strengthened alpha ($\sim 10\text{Hz}$) oscillation in the right intraparietal sulcus (IPS) during the silence after the visual cue and before the sound (i.e., around -0.5s in Figure 1B) while they attended right (i.e., the "Down" stream) and ignored left (the "Up" stream), indicating that spatial inhibitory processing to suppress sound inputs from the left was enhanced; see α oscillation in Figure 1B. Also, middle temporal gyrus (MTG), superior temporal sulcus (STS), and inferior frontal gyrus (IFG) exhibited greater attentional modulation of beta (β : $\sim 25\text{Hz}$) oscillation after the four weeks of training, indicating enhanced neural activity to predict the target voice; see β oscillation in Figure 1B. The strength of attentional modulation on cortical evoked responses to sounds was also improved with training; see Figure 1C left panel. This training effect was transferred to speech-in-noise performance. The accuracy during a separated SiN task was improved after the training

(Figure 1C mid panel) while the auditory cortex evoked response to the target speech during the SiN task was enhanced (Figure 1C right panel). Placebo Group participants did not exhibit any of the above changes (not shown in Figure 1). These results successfully prove the concept that 1) neurofeedback training effectively enhances the cortical processing for auditory selective attention and 2) the training effect is transferrable to a separated SiN task.

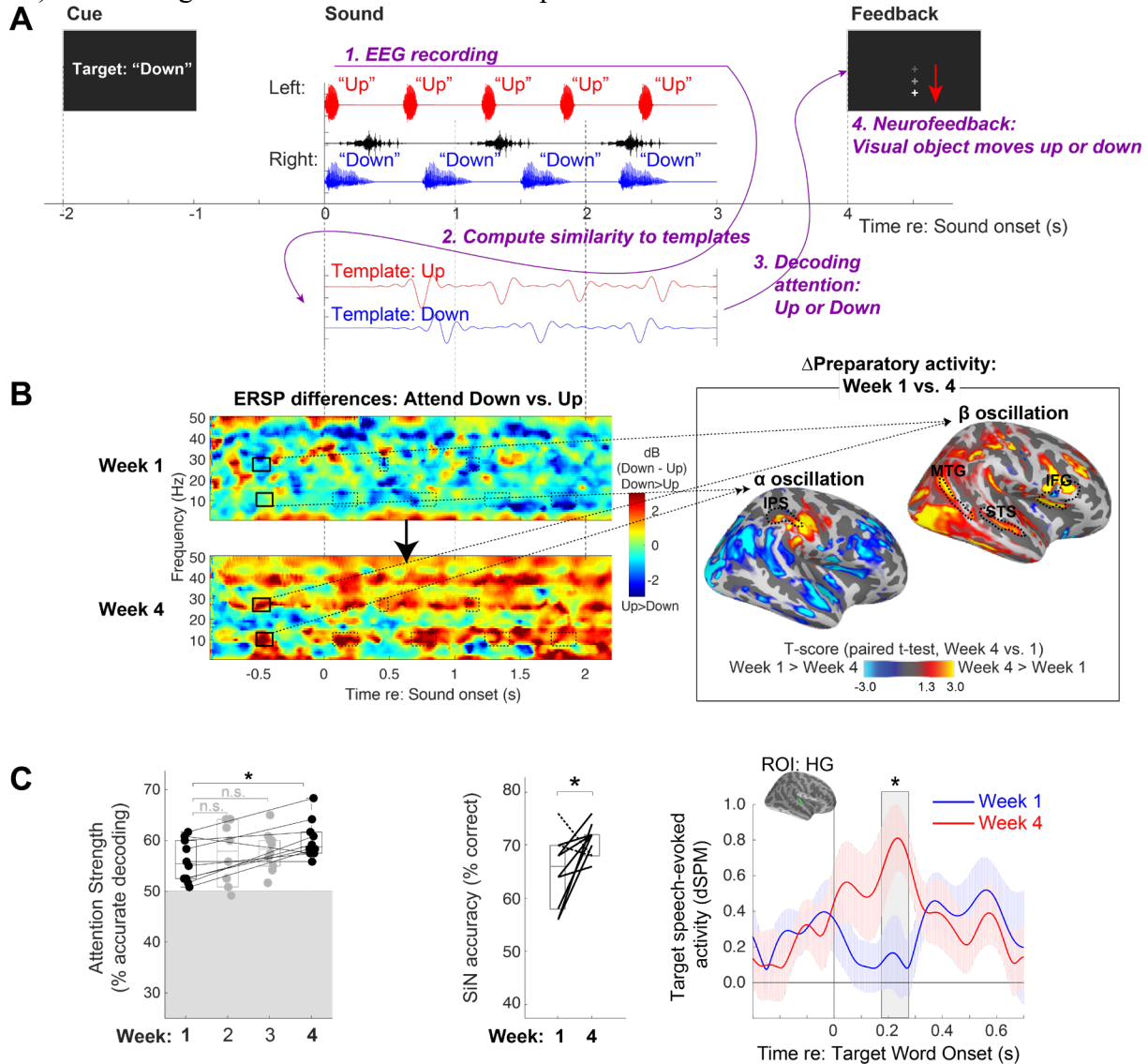


Figure 1. A Trial structure for an example trial attending "Down." **B** Event-related spectral perturbation to show induced oscillatory activities during the training and their changes over time. The spectrograms show grand-average between-condition difference at each time and frequency bin in dB (Attend Down - Attend Up), averaged across all the 64 EEG sensors. Black rectangles at ~-0.5s in the spectrogram indicate clusters that exhibited significant difference between Week 1 and Week 4 from the cluster-based permutation analysis. Within the time range of the rectangles, for each of alpha (~10Hz) and beta (~25Hz) bands, the difference between Weeks 1 and 4 for each cortical voxel (in T-score) is shown on the cortical surface in the right panel. **C** Left: Changes in attentional modulation during training. Attention decoding accuracies from individual subjects are denoted as filled circles over four weeks of training. Middle: SiN accuracy difference between Weeks 1 and 4. Right: The mean time courses of the temporal envelope of evoked source activity.

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.

This project has been providing research experiences to two post-doctoral research scientists, three PhD students, two graduate (Doctor of Audiology) students, a post-bachelor research assistant, and four undergraduate students. The provided research experiences include EEG, ECoG, and behavioral data collection from human subjects, theoretical training of hearing science, and computational analyses of electrophysiological data.

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.

In the next project year, we are planning to finish data collection for all three aims. Based on the findings, we will submit three additional manuscripts to peer-reviewed journals. The very next manuscript that describes differential neural mechanisms of space- and speaker identity-based auditory selective attention is currently being prepared for the submission. The second next manuscript will describe the multiple regression model to predict speech-in-noise performance using peripheral and central auditory factors. The third manuscript will expand our findings from the neurofeedback training of auditory selective attention.

4. **IMPACT:** Describe 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).

This year’s key findings demonstrated that the brain’s efficacy of auditory selective attention improves with neurofeedback training, and improved attention enhances speech-in-noise ability. We learned how to capture such brain plasticity using scalp EEG electrodes. In the future, we will be able use these measures as a clinical monitoring tool for hearing intervention.

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.*

Nothing to report.

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.

Because human subject research was suspended university-wide due to the COVID-19 pandemic in Years 1 and 2, data collection was slower than expected. To achieve all the planned research goals, an 1-year no-cost extension of project period has been requested and approved. Under the revised plan, we will achieve 120 EEG subjects by the second quarter of Year 4 and 12 ECoG subjects by the end of Year 4. The final large-cohort regression analyses and disseminations of results will be performed throughout Year 4.

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

None

Significant changes in use or care of vertebrate animals

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

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).*

During the report period (Sep 2021 – Aug 2022), two manuscripts have been published in peer reviewed journals and four manuscripts have been submitted to peer reviewed journals:

1. Kim, S., Wu, Y.-H., Bharadwaj, H., Choi, I. (Published May 1, 2022). Effect of noise reduction on cortical speech-in-noise processing and its variance due to individual noise tolerance. *Ear and Hearing*. Acknowledgement of federal support: Yes.
2. Geller, J., Holmes, A., Schwalje, A., Berger, J., Gander, P., Choi, I., McMurray, B. (Published Sep 24, 2021). Validation of the Iowa Test of Consonant Perception. *Journal of the Acoustical Society of America*, Acknowledgement of federal support: Yes.
3. Joel Berger and Inyong Choi. Neural correlates of individual differences in speech-in-noise performance in a large cohort of cochlear implant users. Submitted to *Ear and Hearing*, currently in revision. Acknowledgement of federal support: Yes.
4. Jae-Hee Lee, Hwan Shim, Bruce Gantz, and Inyong Choi. Strength of attentional modulation on cortical auditory evoked responses predicts speech-in-noise performance in cochlear implants. Submitted to *Trends in Hearing*, currently in revision. Acknowledgement of federal support: Yes.

5. Hwan Shim, Bruce Gantz, and Inyong Choi. Differences in cortical speech-unmasking processing between listeners with electric-acoustic and electric-only stimulation. Submitted to Hearing Research, currently in revision. Acknowledgement of federal support: Yes.
6. Inyong Choi, Phillip E. Gander, Joel I. Berger, Matthew H. Choy, Jean Hong, Sarah Colby, Bob McMurray, and Timothy D. Griffiths. Spectral grouping of electrically encoded sound predicts speech-in-noise performance in cochlear implantees. Submitted to the Journal of Association for Research in Otolaryngology (JARO). Acknowledgement of federal support: Yes.

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.*

Conference presentation (5):

The following presentations have been made at the Association for Research in Otolaryngology (ARO) meeting (Feb 2022):

- Kayla Howerton, Hwan Shim, Barbara Shinn-Cunningham, and Inyong Choi. Feature dependence of divided auditory attention.
- Hwan Shim, Kayla Howerton, and Inyong Choi. Auditory selective attention during talker-identity cued speech-in-noise task.

The following presentations have been made at the Acoustical Society of America (ASA) meeting (May 2022):

- K Howerton, A Boes, B Shinn-Cunningham, I Choi, Brain perturbation to reveal causal contributions of executive networks to the mechanisms of auditory attention, The Journal of the Acoustical Society of America 151 (4), A257-A258.
- J Hong, H Shim, S Kim, M Hansen, B Gantz, I Choi, Neural correlates of speech in noise perception differences between combined electric-acoustic stimulation and standard cochlear implants, The Journal of the Acoustical Society of America 151 (4), A278-A278.

- H Shim, S Kim, JH Lee, L Gibbs, K Rush, I Choi, Neural markers of improved auditory selective attention following neurofeedback training, *The Journal of the Acoustical Society of America* 151 (4), A257-A257

- **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: Inyong Choi
Project Role: PI
Researcher Identifier: ORCID 0000-0002-6663-9152
Nearest person months worked: 3
Contribution to Project: Conducting all the research activities.

Name: Phillip Gander
Project Role: Co-investigator
Researcher Identifier: ORCID 0000-0003-3945-8820
Nearest person months worked: 1
Contribution to Project: Developed stimuli and experiment scripts for the ECoG study.

Name: Adam Schwalje
Project Role: Resident
Nearest person months worked: 1
Contribution to Project: Developed speech materials for both EEG and ECoG studies.

Name: Sungyoung Kim
Project Role: Subaward PI
Nearest person months worked: 3
Contribution to Project: Developed a wireless EEG system (Aim 3).

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: Rochester Institute of Technology

Location of Organization: Rochester, NY

Partner’s contribution to the project: Collaboration.

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.*