STUDY TITLE:

Hearing Aid Processing and Working Memory in Realistic Spatial Conditions

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STUDY TITLE:
Investigating the relationship between directional microphones, compression, and working memory in realistic spatial conditions.

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Check any **applicable** boxes in the table below – you will be asked for further detail on these topics later in the protocol form:

Indicate Vulnerable Population(s) to be Enrolled	☐ Children ☐ Cognitively Impaired Adults ☐ Pregnant Women (IF the research activities will affect the pregnancy or the fetus) ☐ Prisoners (or other detained/paroled individuals)
International Research (check this box if you will collect data from individuals located outside the United States)	☐
Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates)	☐
Research has U.S. Federal government funding (e.g., NIH, NSF, other federal agencies/departments)	☒

1.0 Purpose of the study:

The purpose of this research is to understand how patient variables interact with hearing aid signal processing in realistic listening conditions in order to effectively treat hearing-impaired individuals in communications situations that are most important to them.

2.0 Background / Literature Review / Rationale for the study:

Hearing loss is prevalent in approximately 37 million adults over the age of 18 years in the United States [1]. Hearing aids are the typical rehabilitative approach for most individuals with permanent hearing loss. While there is evidence that hearing aid use significantly improves the quality of life [2-4], hearing aid adoption rates are as low as 30% [4,5], due to lack of perceived benefit in difficult listening environments [3]. If hearing loss is not treated adequately, it can lead to broader consequences including social isolation and depression [6,7]. Therefore, an individualized approach to hearing healthcare including selection of hearing aids and customization of settings to the listener's abilities and environment, is integral to adherence to treatment, social engagement, and listener satisfaction [8]. The central focus of this research proposal is to inform the choice of hearing aid settings based on individual variability.

Signal modifications caused by collective hearing aid processing and environmental conditions affect individual benefit from hearing aids. An important relationship that has heavily influenced audiology practice is the finding that listeners with lower working memory capacity are disadvantaged by hearing aid signal processing that substantially modifies the speech signal (such as fast-acting wide dynamic range compression, or WDRC [9,10]). In response to this finding, researchers and some hearing aid manufacturers have advocated for less aggressive signal modification (such as slow-acting WDRC, which gradually adjusts hearing aid gain) and others have suggested that measurement of working memory or other cognitive abilities should be part of the clinical hearing aid fitting process.

Importantly, the relationship between working memory and WDRC is strongest under adverse listening conditions (e.g., high levels of background noise [9-12]) and diminished in ideal listening conditions (e.g., speech in quiet [9-12]). However, there is a critical limitation of the research that has supported this conclusion. All previous studies on this topic assumed the use of omnidirectional microphones in unrealistic spatial conditions, such as co-located speech and noise. Such conditions fail to recognize that most hearing aids are fit with directional processing that may improve the listening environment [13, 20], and that typical environments contain speech and noise signals in a range of spatial locations. Further complicating this issue, directional microphones vary in the amount of benefit across listening conditions [13]. Therefore, the proposed research aims to understand how the relationship between working memory and WDRC changes in the presence of microphone directionality in different listening conditions.

The aims of this study are: 1) to examine the relationship between working memory and hearing aid signal processing (WDRC in the presence of microphone directionality) in spatial conditions *ideal* for directionality, 2) to examine the relationship between working memory and hearing aid signal processing (WDRC in the presence of microphone directionality) in *realistic* spatial conditions.

The proposed research will help answer whether working memory remains an important variable to measure when microphone directionality and WDRC features are used in combination, thus providing evidence for whether working memory should be added to the standard hearing aid fitting protocols.

3.0 Inclusion and Exclusion Criteria:

Inclusion criteria:

- 18 years or older
- Sensorineural hearing loss with pure-tone thresholds between 25-70 dB HL at octave frequencies between 500 and 3000 Hz
- Speak English as their primary language
- Normal or corrected-to-normal vision (<=20/50)
- Participants will be in good health (self-report)

Exclusion criteria:

- Clinically significant unstable or progressive medical conditions
- Participants who score <23 on the cognitive screening test (Montreal Cognitive Assessment)
- Evidence of conductive hearing loss or middle ear issues
- Significant history of otologic or neurologic disorders
- Evidence of significant asymmetry between ears
- Non English-speaking or non-native English speaking

We may enroll a small group (n=30) of listeners with normal hearing, defined as pure-tone thresholds of 25 dB HL or less at octave frequencies between 250 and 3000 Hz. This group may be enrolled for the purposes of test validation, or to study the effects of hearing loss on the outcome measures. With the exception of having normal hearing, those participants will follow the inclusion and exclusion criteria described above.

The study will not recruit special populations such as adults unable to consent/cognitively impaired, minors, prisoners, or other detained individuals.

4.0 Sample Size:

The study will recruit 120 participants over a 3-year period. Each experiment will recruit approximately 30 participants (additional 10 account for pilot testing and attrition) for a total of 3 experiments.

Sample size considerations were based on the primary analyses of a mixed effect model with fixed effects for WDRC, working memory, and the interaction.

Simulations were performed based on a range of effect sizes and estimates of between subject and within subject variances. Our sample size of 15 subjects per working memory (high vs low), will provide at least 80% power to detect reasonable effect sizes for all three effects. Specifically, we assumed a conservative subject variance estimate of 0.01 and a residual variance estimate of 0.01 from pilot data, marginal effects for working memory of 0.70 (high) and 0.53 (low), and marginal effects for WDRC of 0.75 (fast) and 0.48 (slow). In simulations assuming a two-sided type one error, we had adequate power to detect all three effects. In simulations assuming less conservative variance estimates, our sample size will provide adequate power to detect even smaller effect sizes. Specifically, we assumed a subject variance estimate of 0.008 and a residual variance estimate of 0.006, marginal effects for working memory of 0.38 (high) and 0.17 (low), and marginal effects for WDRC of 0.33 (fast) and 0.22 (slow). We anticipate a range of effect sizes and variance estimates for models within each level of directionality, and thus considered simulations from a range of assumptions.

5.0 Recruitment and Screening Methods:

Recruitment process:

The proposed study will recruit 120 adults (18 years or older) over a three year period. Participants will be primarily recruited from an existing database in the lab that has over 300 adults with hearing loss who are interested in study participation and agreed to be contacted for future research. The lab also has access to a Communication Research Registry, a confidential database for individuals interested in continuing research participation within the Northwestern School of Communication. Additional recruitment will take place through the department's audiology clinic, local senior centers, and local Hearing Loss Association of America (HLAA) chapter using flyers. Recruitment flyers will also be disseminated through flyers on bulletin boards throughout the Northwestern campus. Advertisements will be posted in local boards.Interested participants will be contacted by the research staff via phone or email as preferred by the potential participant. At this time, the participant will be provided basic information regarding study procedures and inclusion criteria.

Screening process:

Prior to enrollment in the study, potential participants will go through a screening process. The screening procedure will take approximately 60-80 minutes. The following tests may be conducted to verify eligibility for research inclusion:

Test	Description/Purpose	Exclusion Criteria
Case history	Written administration; questions re: onset/nature of hearing loss, hearing aid use, otologic and medical history; CEDRA questionnaire [21]	Significant history of otologic/neurologic disorders
Otoscopy	Visual examination of pinna, ear canal, and ear drum	Significant impaction of wax, active discharge; exclusion will be determined in

		conjunction with tympanometry when appropriate
Tympanometry	Test to determine middle ear status	B-type tympanogram suggesting unhealthy middle ear status
Audiogram*	Air conduction (250 Hz to 8000 Hz) and bone conduction (500 Hz to 4000 Hz) testing to determine degree and type of hearing loss	Evidence of conductive hearing loss (air-bone gap > 10 dB HL); Hearing loss > 70 dB HL at any frequency between 250-3000 Hz; Evidence of significant asymmetry between ears (≥ 15 dB HL at 3 or more frequencies OR ≥ 20 dB HL at any 2 frequencies) [14]
Monosyllabic word recognition	Percentage of phonetically-balanced words repeated in quiet at a comfortable loudness.	Evidence of significant asymmetry between ears [15]
Montreal Cognitive Assessment (MoCA) [16]	Cognitive screening test that assesses orientation to time and place, short-term memory, and ability to follow simple commands	The scope of this study does not include cognitive impairments, therefore, we will exclude participants with a score lower than 23 [17] (suggests dementia)
Vision Screening	Screen for normal or corrected-to-normal vision using a letter/number chart	Normal/corrected-to-normal vision is required because the study involves selection of response options seen on a computer screen. MoCA (above) involves identifying/copying visual objects. We will exclude subjects who fail vision screening.

All participants must be native speakers of English because our outcome measure is speech intelligibility of English sentences [18] from a local talker database. Therefore, proficiency in English (based on self-report) is required for the validity of the results. The participants should also be in general good health (based on self-report).

*During the COVID-19 pandemic, it may not be possible to obtain new audiograms in the lab due to risk of exposure to both the participant and the research staff. For participants recruited from outside our lab pool or any participant who does not have a valid audiogram, we may adopt the following procedures:

a) Request the participant to provide a copy of their existing audiogram (if available) completed by an audiologist outside of our lab. The participant will be asked to upload a copy of their hearing test via REDCap. If a participant is unable to access REDCap, they can send a copy of their hearing test via fax or to an encrypted email address.
b) We may obtain air conduction thresholds using a validated remote automated test (e.g., GSI AMTAS Flex [22]) delivered to the participant via a tablet and calibrated headphones. The participant will be asked to complete the test in a quiet room with minimum distractions. The automated hearing test is HIPAA-compliant and FDA-registered.

Additional explanation:

Our study population is adults with hearing loss. Therefore, we will include individuals with sensorineural hearing loss with pure-tone thresholds between 25-70 dB HL at octave frequencies between 500 and 3000 Hz. This meets the criteria for a mild to moderately-severe hearing loss. This is the typical range of hearing loss for which individuals seek hearing aids and also the range for which hearing aids can provide sufficient gain. Participants should have no significant history of otologic or neurologic disorders as these disorders are beyond the scope of the study. The participant must have normal or corrected-to-normal vision because the cognitive tests involve visual (reading) tasks. Exclusion criteria include conductive hearing loss and middle ear issues (e.g., active discharge, significant wax impaction) as these conditions may preclude the use of a hearing aid and are outside the scope of the study. Exclusion criteria also includes asymmetry between ears [16]. Asymmetry between ears may require different hearing aid settings for each ear which may confound the results. Participants who do not pass the cognitive screening test (< 23 on the Montreal Cognitive Assessment [16, 17]) will also be excluded because cognitive impairments are beyond the scope of this study.

6.0 Research Locations:

The proposed work will be conducted within the Hearing Aid Lab (PI: Dr. Pamela Souza) and in a virtual sound room (ViSoR) at Northwestern University. The lab is a 600 square foot space that includes an 8’ x 8’ double-walled IAC sound booth. The lab also has a meeting area with a large desk and chairs for case history-taking, cognitive assessments, and counseling, a participant waiting area with educational materials on hearing loss resources and support, and a secure file storage area. The research may also be conducted in a separate 10’ X 7’ sound-treated space (Frances-Searle room 1-387) that has been recently added as part of the Hearing Aid Lab.

The virtual sound room (ViSoR) is within the Northwestern University Center for Audiology, Speech, Language and Learning (NUCASLL) in a building adjacent to the Hearing Aid Lab. The research staff involved in this study have access to this room.

Due to the COVID-19 pandemic, participant research visits may be conducted remotely using Northwestern IT-approved (and HIPAA-approved) video conferencing or phone. The research staff will conduct these visits from a private room in their apartment and no one else will be present during the research study. The research staff may also conduct these virtual visits from the hearing aid lab or an office space. Participants will perform the remote testing from their respective places of residence/a quiet place of their convenience. The virtual visits will be conducted either through Zoom or Microsoft Teams or WebEx applications. The platform used will be determined by participant preference.

7.0 Multi-site Research (research that involves external collaborating institutions and individuals): N/A

8.0 International Research (where data collection will occur outside the United States and U.S. territories): N/A

9.0 Procedures Involved:

The proposed research will measure speech intelligibility and signal fidelity with a combination of hearing aid settings under a variety of spatial conditions (Aim 1: ideal; Aim 2: realistic) for hearing-impaired listeners with different working memory capacities. The proposed research is a clinical trial and will use laboratory hearing aids to provide various combinations of hearing aid signal processing. Using a mixed design, individual variability in auditory and working memory capacity will be related to speech intelligibility and signal fidelity across test conditions. Test procedures including stimuli and outcome measures described below are common to both Aims 1 and 2.

Study tasks for all experiments will include the following steps per subject:

Session 1	**Approx. Duration (2 hours)**	**Session 2**	**Approx. Duration (2 hours)**	**Session 3**	**Approx. Duration (2 hours)**
Candidacy assessment	60-80 mins	Earmold + Hearing Aid Fitting	45-60 mins	Outcome measurement (Speech intelligibility testing, localization) continued	60-120 mins
Cognitive test*	15-30 mins	Outcome measurement (Speech intelligibility testing)	60 mins		
Earmold impression	15-20 mins				

*May include tests of working memory, executive function, and processing speed

Session 2 will take place ~10-15 days after session 1 to allow for time taken for the custom earmold order to be received. There is no minimum gap required between sessions 2 and 3. Session 3 may not be required for all experiments or participants.

Stimuli:
Recorded speech materials (words, sentences, or passages) will be presented. These speech materials will be combined with multi-talker babble at varying levels (including no noise), and the intensity of the stimuli will be adjusted to represent typical conversational speech (65 dB SPL).

The listener will be fit with hearing aids that are either commercially available or an open-platform hearing aid or a computer simulation of a hearing aid [e.g., 9] that allows flexible adjustments compared to commercial hearing aids and ensures adequate scientific rigor. The hearing aids will be fit to a foam/ear tip or a custom earmold and the amplification levels will be set appropriate to the individual's hearing. If a computer simulation is used, the amplified/processed sounds will be presented via headphones or earphones and the amplification levels will be set appropriate to the individual's hearing.

Earmold impression: First, the ear is visually inspected with an otoscope (lighted magnifying scope). Then a cotton/foam block and soft impression material are placed in the ear. The material is left to set for about 3 mins after which it is removed along with the cotton/foam block and is used to order an earmold for later testing. This is a standard clinical procedure.

Loudness discomfort levels: Participants will be played sounds at progressively louder levels and asked to verbally indicate the maximum point of listening comfort. Loudness discomfort levels will be measured at 0.5 and 3 kHz and used in combination with patient report. This is a standard clinical test used to verify that stimuli levels are not uncomfortably loud.

Hearing aid fitting: The ear is visually inspected using an otoscope. A small soft plastic tube is inserted into the ear canal and is used to measure the sound output of the hearing aid. The hearing aid + earmold are placed in the ear. The participant is seated in front of a speaker and sound is played from it. The sounds may be speech or noise with similar frequency content to speech, at levels ranging from soft to conversational to loud speech (50-80 dB SPL). In order to verify that the hearing aid is not uncomfortably loud, a stream of loud beeps (85-90 dB SPL) are played for 2-3 secs. Alternatively, the hearing aid fitting may be completed in a test box with a standard coupler instead of the participant's ears. These are standard clinical procedures used to adjust the hearing aid so that the programming settings are appropriate for the participant's hearing loss. Recently, hearing aid manufacturers have included the capability to fit hearing aids remotely. If needed, hearing aids may also be fit remotely using hearing aid manufacturer-specific software.

Outcome measures:

Speech recognition: The recorded speech materials that have been electronically processed and mixed with multi-talker babble, will be presented through earphones or speakers. The speech material and noise may be presented through single or multiple speakers and from different locations in the test room. The participant will listen through the hearing aids for the duration of the experiment. The participant's task would be to either repeat the speech or select it from a list of choices on a computer monitor or provide a written response.

To minimize contact with the participant during the COVID-19 pandemic, the participant may be provided with a tablet or computer monitor to control (using a touchscreen, keyboard or mouse) the presentation of the stimuli via a graphical user interface. The participant will be recorded repeated the speech so that their responses may be scored later by the experimenter (also see section 17). The participant will be guided with on screen instructions and may reach the experimenter via an intercom at any time.

Localization: Listeners may be asked to indicate where they perceive a sound to have originated. The sounds may be presented through speakers or headphones. Responses may be given verbally or via an interface using a touch screen or keyboard and mouse. Since hearing aid processing (e.g., directional microphones) is known to affect localization of sounds [23], this measure may provide additional insights into hearing aid outcomes.

Working memory task: The Reading Span test (RST [19]) will be used to measure working memory for each participant. The participants are instructed to read a set of sentences presented on a computer screen, one at a time, and make a judgment about the meaningfulness of each sentence. After a set of 3-6 sentences they are asked to recall either the first or last words of all the sentences. Scores are based on the number of words correctly recalled in each set.

Audio Visual Divided Attention Task (AVDAT; [25]): The AVDAT is comprised of three span tasks: auditory, visual, and dual (auditory and visual). Participants are presented with either letters or numbers, depending on the test, and their task is to correctly recreate the given sequence. The test progresses by adding one number or letter to the previous span and ends after three consecutive incorrect responses have been submitted, thereby pinpointing a participant's working memory span.

Executive function: This is the strategic control of mental processes and determines how cognitive resources are allocated to various tasks.

The Stroop Test. This is a measure that assesses reaction time and conscious versus automatic visual processing. This test takes approximately 5 minutes to administer. Participants are instructed to read black text that indicate the names of colors, as quickly as possible. The second part of the assessment includes participants seeing colored lines, and they are instructed to name the colors on the page as quickly as they can. The third part of administration is the participant will then be given a list of color names, where they say the color of each word, not read the text itself. For example, if the word “yellow” was written in green ink, the correct response is “green”. Participants are timed for each of the three segments.

The Flanker Test: We will administer two tasks tapping this interference control ability and compute a z-score aggregate to obtain a stable estimate. In the arrow

flanker task, participants see a > or < sign, surrounded by two > or < signs on either side (e.g., >>>>>, <<><<). Their task is to focus on the middle sign and decide whether that sign is pointing to the left or the right as quickly and as accurately as possible by pressing one of the two buttons (left or right). The reaction time difference between the compatible (e.g., >>>>>) and incompatible stimuli (e.g., <<><<) will be used to index interference control ability. In the letter flanker task, participants will see either a letter G or H in the middle, surrounded by two Gs or Hs on either side (e.g., HHHHH, GGHGG). Participants' task is to focus on the middle letter and determine as quickly and as accurately as possible whether it is a G or an H. Again, the reaction time difference between the compatible (e.g., HHHHH) and incompatible (GGHGG) stimuli will be used as the index of interference control ability.

Processing speed: This is the rate at which information is treated in the cognitive system. Individuals with higher processing speed are expected to have better outcomes especially when the conditions are more challenging.

WAIS-III Coding/Symbol Search [24] (3 minutes): Participants are presented with a series of letters and a key at the top of the page with a corresponding number. Below each letter is a space to write the corresponding number, and participants are asked to fill in as many of the numbers as they can within a certain amount of time.

Rationale for including additional cognitive measures: The above-described measures including AVDAT, measures of executive function, and processing speed may be included to explain variability in outcomes that may not be captured by the reading span test.

Peripheral auditory abilities: Participants may be asked to listen to tones, sounds of different frequencies and modulation, or noises of different lengths to determine auditory abilities beyond simple hearing thresholds. These measures are quick, non-invasive, and are presented at safe listening levels (i.e., 65-75 dB SPL) and pose little to no physical risk to participants. These sounds will be presented over headphones or speakers in a sound-treated room and may take 30 minutes to complete.

Acoustic measurements: After the completion of experiment by the participant, de-identified hearing aid fitting data may be retrieved from NOAH, the hearing aid programming software for additional analysis. This hearing aid fitting data may be programmed back onto the hearing aid in order to record output on an acoustic manikin within the same test conditions as the behavioral experiment. The recorded output will be used to measure signal fidelity across conditions and relate acoustic measurements with speech intelligibility and individual patient characteristics such as age, degree of hearing loss, and cognitive abilities. This part of the experiment does not directly involve the participant and will only be conducted with de-identified materials.

Additional procedures for remote data collection: If the participant is provided a tablet and calibrated headphones for automated audiometry, the following procedures will be used. The participant will be provided with detailed instructions on the phone or through a HIPAA-compliant video conferencing platform. The participant will be requested to complete the testing in a quiet location, with minimum distractions. In order to monitor the surrounding noise levels during the testing, the participant may be asked to record the noise levels in their room using a publicly available sound level meter application (e.g., Decibel X, NIOSH SLM). Obtaining a record of the noise level during the testing is important as high background noise may obscure the results of an audiogram.

No identifiable information will be placed on the tablet at any stage of the experiment. Completed data from each participant will be retrieved from the tablet (and erased) and housed on a secure server, before providing the tablet to the next participant.

The remote testing equipment (tablet(s) and calibrated headphones) will be provided to the participant using one of the following methods (depending on convenience):

a) The participant may pick up the equipment from a research staff member from the curbside/parking lot by the Frances-Searle building. The participant may also return the equipment to the research staff member at the same location, upon completion of the experiment.
b) The equipment may be delivered to and picked up from the participant's residence by a research staff member.
c) The equipment may be mailed to the participant with a return box and shipping label.

Communication regarding the details of pickup and return of the equipment (including preferred method and date/time/location) will take place over the phone or via email. A record of the agreed upon details will be maintained by the research staff. The participant will be sent a reminder 24 hours before the scheduled time, either via email or phone (depending on the participant's preferred method of contact). A tracking number will be associated with any shipments and the package will be insured. In the event that the participant does not return the equipment by the agreed upon time/date, we will follow up with reminder emails or phone calls to determine the cause for delay and to provide them with alternative options for returning the equipment within a reasonable time frame. Participants will not be charged and financial compensation will not be withheld in the event of loss or damage to any equipment.

We will adhere to strict infection control procedures by thoroughly cleaning all surfaces of the tablet and headphones before and after a participant has used them. In addition, we will maintain 2-3 sets of equipment to reduce the number of users of the same equipment.

10.0 Research with Vulnerable Populations: N/A

11.0 Incomplete Disclosure or Deception: N/A

12.0 Consent Process:

Prior to enrollment in the study, potential participants will have a hearing, vision, and cognitive test with authorization by a screening consent form. These tests will allow us to exclude potential participants who are ineligible based on their hearing, vision, or cognitive status from enrolling in the study. These tests will be built into the first visit tasks and will last 60-80 minutes. If the participant is eligible based on the screening process, he/she will be consented for the experimental procedures using a separate form. If a participant is not eligible based on screening, they will have the option to authorize future contact and authorize the lab to retain the screening audiogram and cognitive test results. Consenting will take place in the Hearing Aid Lab, prior to any research procedure taking place. All consent forms are stored in a locked file cabinet within the Hearing Aid lab (locked lab). The potential participant will be provided unlimited amount of time to review the consent forms and ask any clarifying questions. Following the participant's opportunity to review the consent form, the researcher will review each section with the participant to clarify any study procedure and ensure understanding. All participants will be offered a copy of their signed consent form with the option to decline. The researcher will document the consent process and the participants' receipt of/decline of a signed copy on a study flow sheet. Both participant and staff will initial the flow sheet to verify that the consent form was provided or that a copy was declined.
Please note that during the consent process, the researcher will explain to the participant that their identifiable information will be kept confidential and will not be used.

Due to the COVID-19 pandemic, virtual consent will be obtained from any newly enrolled study participants in order to minimize risk of exposure. Participants will be consented using one of two procedures, determined by participant preference:

Option 1: The participant will be consented electronically using REDCap. The participant will be required to "sign" by typing their name and enter the date. The participant will be able to review the consent form as many times as they need to, go back and forth through sections, and take their time before providing their consent. They may save their progress on the form and return to it at a later time if needed. The participant may contact a study team member as needed to provide any clarifications regarding any part of the consent form via phone or email or video before the deciding to provide their consent. All information required for informed consent will be available on the eConsent forms. Consent forms for this study do not have any associated external material or hyperlinks. In order to ensure the identity of the signer, the REDCap consent form can only be accessed by the email address that it is sent to (i.e., the email address provided by the

participant). In addition, the participant will be provided with a predetermined passcode via phone or video. At the time of accessing the electronic consent form, the participant must enter the passcode which will be internally compared with the stored version entered by the study team member. The participant will be granted entry only if the passcode matches. The participant will have the option of saving a copy of their signed eConsent forms as PDFs. A study team member will review the submitted eConsent form and electronically sign and date as confirmation.

Option 2: The participant will be sent a consent form via encrypted email, which they will sign and date, scan/take a photo of, and email back to the research staff. The participant may contact a study member as needed to provide any clarifications regarding any part of the consent form via phone or email or video before the deciding to provide their consent. The staff member will review the submitted consent form and sign and date as confirmation. The participant will be sent a scanned copy of the signed consent form for their records.

13.0 Research with Children – Parental Permission, Child Assent, and Other Considerations: N/A

14.0 Waiver of Participant Signature on Consent Form: N/A

15.0 Waivers and Alterations of Consent Information: N/A

16.0 Financial Compensation:

Upon completion of the study tasks, the participant will be paid an hourly rate for participation ($15/hour). Payment will be made in cash at the conclusion of each session. If the participant decides to withdraw from the study before its completion, he/she will be paid $15/hour for the time spent. There is also dedicated parking space for research participants (at no charge) and an accessible entrance to the lab building.

Due to the COVID-19 pandemic, participants will be given the option of being compensated at the above rate in the form of a Hyperwallet Virtual Card provided by Northwestern University in order to minimize the risk of exposure. The card will be issued at the completion of the study visit at which point the participant will be emailed instructions for the card activation process. For participants who do not have access to email, they will also be given the option of being issued a check or a physical gift card for the amount that they are owed. Financial compensation will not be withheld in the event of loss or damage to any experimental equipment.

17.0 Audio/Video Recording/Photography

Audio and video recordings may be obtained during the screening tests and the listening tasks. The purpose of the audio/video recordings is to ensure accuracy (a second scorer may listen to the recordings and correct any potential errors). The recordings will contain only non-identifiable information and will be destroyed 3 years after the completion of the study. Audio and video recordings will not be obtained during earmold impressions and hearing aid fitting.

18.0 Potential Benefits of this Research:

Participants in this study may not directly benefit from the experiment. The findings from this research can result in improvements in clinical decision-making for hearing aid fittings and audiological care. Therefore, participants with hearing loss seeking hearing aids may benefit in the long-term. Many participants are interested in hearing aid research as an opportunity to get information and ask questions about hearing aids without sales pressure. All participants will have the opportunity to receive counseling at the end of the study, by the investigators or the research coordinator, all of whom are also trained and certified audiologists. Counseling, if and when provided, will include listening recommendations tailored to their individual speech understanding and memory. Participants will have the chance to ask questions and receive information about options for their hearing loss (outside the study).

19.0 Risks to Participants:

All study procedures pose minimal risk to participants. There is potential that the study task might be boring or repetitive, and therefore if a participant wishes to discontinue testing at any point, they may choose to do so without any consequence. Listeners who receive poor scores on the cognitive tests may be disappointed to learn of their performance. Some listeners may find the sounds processed through the hearing aid simulator to be sharp or tinny in comparison to their unaided hearing. These are normal and expected consequences of any hearing aid fitting. Loudness discomfort levels will be measured and presentation levels will be monitored to ensure that levels never become uncomfortable. When the earmold impression is taken, participants may experience some temporary discomfort or a ticklish feeling as the cotton/foam block is placed into the ear canal. Participants may also notice that the impression material is slightly cold, or experience a feeling of pressure while the impression material is in your ear. Rarely, there can be some minor abrasions to the skin of the ear canal. These procedures are routinely used when fitting hearing aids or creating custom earplugs and the risks in this study are no higher than the risks that would be experienced in an audiology clinic.

The hearing aids and earmolds will only be used for the duration of the experiment. The participant is free to remove the hearing aids and/or leave the test booth at any time. Participants are encouraged to take breaks and can discontinue the study at any time without penalty. If the investigator determines participation

in the study places a participant at unacceptable risk, enrollment or study tasks will not proceed.

Participant confidentiality will be ensured by storing data without subject identifiers. Data files are password protected and can only be accessed by authorized lab members. Hard copy data are stored in locked file cabinets within a restricted-access laboratory space. All study staff complete training in ethical procedures for working with human subjects and in HIPAA regulations.

If a research participant decides to withdraw or discontinue study procedures, all data collected up to that point can be used by the investigator unless the participant indicates that they would like to have their data removed from the study. In the event that a participant is removed from the study without their consent, compensation will be pro-rated based on the duration the participant remained compliant with study tasks and procedures.

In the event that a participant is compensated using the Hyperwallet Virtual Card, an account will need to be created using the participant's name and email address, which will link their name to the study. This creates a small additional risk of breach of confidentiality.

20.0 Provisions to Protect Participant Privacy and Data Confidentiality:

All experimental procedures will be conducted in the Hearing Aid Lab at Northwestern University. The data for this study will include audiometric thresholds, age, cognitive measures, speech intelligibility scores, hearing aid fitting data, and acoustic measurements. Participant responses recorded through the computer interface will be coded and will not contain any identifiable information. All data will be de-identified prior to analysis. De-identification will take place by assigning a particular code to all data pertaining to one subject. The link between the subject code and the subject name will be stored in a password-protected file on a HIPAA-approved server managed by Northwestern School of Communication computer support staff. This information will also be stored on the secure REDCap database. Participant identifiers will be stored electronically on REDCap in a separate instrument than the study data. REDCap will also be used to track study data. All research staff will receive appropriate Human Subjects protection training and training regarding confidentiality. Data are only accessible by the study staff via password-protected files. Discussion regarding subject confidentiality will also be included during regular lab meetings.

21.0 Data Monitoring Plan to Ensure the Safety of Participants:

All experimental procedures will be conducted in the Hearing Aid Lab and the virtual sound room at Northwestern University. The data for this study will include audiological data, age, cognitive measures, and speech intelligibility scores, hearing aid fitting data, and acoustic measurements. Participant responses recorded by the experimenter through the computer interface will be coded and

will not contain any identifiable information. Any audio-recording done for the purpose of scoring will also be de-identified and will be deleted at the end of the experiment. All data will be de-identified prior to analysis. De-identification will take place by assigning a particular code to all data pertaining to one subject. The same subject code will be used in the hearing aid programming software. The link between the subject code and the subject name will be stored in a password-protected file on a HIPAA-approved server managed by Northwestern School of Communication computer support staff. All research staff will receive appropriate Human Subjects protection training and training regarding confidentiality. Data are only accessible by the study staff via password-protected files. Discussion regarding subject confidentiality will also be included during regular lab meetings.

The proposed research uses a very low-risk intervention (i.e., hearing aids). The investigator(s) will be responsible for ensuring participants' safety at the time of experimentation. If the investigator(s) determine that participation in the study places a participant at an unacceptable risk, enrollment or study tasks will not proceed. The participants will use the laboratory hearing aids only for the duration of the experiment. Therefore, the use of the intervention will always be monitored by the experimenter. The co-investigator is responsible for making the ear impressions and completing the hearing aid fitting. All testing will be conducted by an investigator, the research study coordinator, or a research assistant. The research assistant will be supervised by an investigator or the research study coordinator. The investigators as well as the research study coordinator are trained and licensed audiologists and have several years of experience in conducting hearing assessments, hearing aid fitting, and research with adults and are therefore qualified for monitoring the study.

22.0 Long-term Data and Specimen Storage and Sharing: N/A

23.0 Qualifications of Research Team to Conduct the Research:

Our team has extensive experience in human research and all members are CITI (Collaborate Institutional Training Initiative) certified:

- Pamela Souza is a researcher and a licensed audiologist who has more than 20 years of experience studying hearing aids and speech perception.

- Varsha Rallapalli is a research assistant professor who has significant experience in human research and is also a trained and licensed audiologist and a researcher with over six years of human research experience. Her research expertise is in the area of speech perception, modeling, and hearing aids.

- Kendra Marks is a research study coordinator in the Hearing Aid Lab. She is a trained and licensed audiologist and has over eight years of experience

in hearing testing, hearing aid fitting, and counseling patients with hearing loss as well as significant experience in human research.

- Research assistant on the study who will assist with data collection and analysis will be a graduate student in audiology who is receiving training in assessment and rehabilitation of hearing-impaired individuals. The research assistant will also be CITI certified.

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