University of Illinois at Urbana-Champaign
Office of the Vice Chancellor for Research

Certificate of Completion
Human Subjects Research Education Module

This is to certify that

Woojae Han

Completed our Human Subjects Research Education Module
on

03 April 2008

Sue Keehn
Director, IRB

Ref No: **whan5103**

University of Illinois at Urbana–Champaign

Institutional Review Board Office
528 East Green Street, Suite 203, MC-419
Champaign, IL 61820
tel: 217-333-2670
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IRB-1

Application for Review of Research Involving Human Subjects

Irb-1v2 14

This Section is for Office Use Only

UIUC IRB Protocol No. _____ Track: _____

Exempt under 45 CFR §46.101(b) ☐(1) ☐(2) ☐(3) ☐(4) ☐(5) ☐ (6) Reviewer 1: _____

Expedite, Category ☐(1) ☐(2) ☐(3) ☐(4) ☐(5) ☐(6) ☐(7) ☐(8) ☐(9) Reviewer 2: _____

All forms must be completed, signed by the RPI, and submitted by FAX, Email, or single-sided hard copy.

Please, no staples!

1. RESPONSIBLE PROJECT INVESTIGATOR (RPI) The RPI must be a nonvisiting member of UIUC faculty or staff who will serve as project supervisor at UIUC. Students, interns, post-doctoral researchers, and visiting faculty from other campuses may not serve as RPI, but should be listed as Investigators, if applicable (see Part 3, below).

Last Name: Allen	First Name: Jont	Academic Degree(s): Ph.D	
Dept. or Unit: ECE	Office Address: Beckman Institute		Mail Code: MC-251
Street Address: 405 N. Mathews	City: Urbana	State: IL	Zip Code: 61801
Phone: 217-244-9567	Fax:	E-mail: jontalle@illinois.edu	
UIUC Status: Nonvisiting member of (Mark One) ☒ Faculty ☐ Staff			

2. PROJECT TITLE

The Effect of SNR-Loss on Consonant Confusions

3. INVESTIGATORS List all investigators who are different from the RPI, including those from other institutions. Include all persons who will be directly responsible for the project's design or implementation, the consent process, data collection, data analysis, or follow-up. Collaborators, outside consultants, and graduate and undergraduate students should be listed if they will be responsible for these activities. Include all investigators named on grant proposals.

Last Name: Gooler	First Name: David	Academic Degree(s): Ph.D	
Dept. or Unit: SHS	Office Address: Speech and Hearing		Mail Code: Mc-482
Street Address: 901 S. Sixth St.	City: Champaign	State: IL	Zip Code: 61820
Phone: 217-244-2542	Fax: 217-244-2235	E-mail: dgooler@illinois.edu	
Affiliation:	UIUC ☒ Faculty ☐ Staff ☐ Grad Student ☐ Undergrad Student ☐ Visiting Scholar, or ☐ Non-UIUC Affiliate of (Institution):		

Last Name: Han	First Name: Woojae	Academic Degree(s): MS	
Dept. or Unit: SHS	Office Address: speech and Hearing		Mail Code: MC-482
Street Address: 901 South Sixth St.	City: Champaign	State: IL	Zip Code: 61820
Phone: 217-217-1378	Fax:	E-mail: whan5@illinois.edu	
Affiliation:	UIUC ☐ Faculty ☐ Staff ☒ Grad Student ☐ Undergrad Student ☐ Visiting Scholar, or ☐ Non-UIUC Affiliate of (Institution):		

List additional Investigators on an attachment and check here: ☒

4. RESEARCH STAFF. List other research personnel who should be copied on IRB Office correspondence for this study.

Last Name:	First Name:	Academic Degree(s):		
Dept. or Unit:	Office Address:		Mail Code:	
Street Address:	City:	State:	Zip Code:	
Phone:	Fax:	E-mail:		
Affiliation:	UIUC ☐ Faculty ☐ Staff ☐ Grad Student ☐ Undergrad Student ☐ Visiting Scholar, or ☐ Non-UIUC Affiliate of (Institution):			

List additional Research Staff on an attachment and check here: ☐

5. FUNDING Indicate whether this research is funded by, or application has been made for, a grant, contract, or gift.

5A. STATUS
☒ Research is **not funded** and is **not pending** a funding decision (Proceed to Part 6).
☐ Research is **funded** (funding decision has been made).
☐ Funding decision is **pending**. Funding proposal submission date:

5B. SOURCE(S) If the research is funded or pending a funding decision, mark and name all sources:

	Type of Funding—check all that apply	**Name of Source**
☐	**UIUC Department, College, or Campus** (includes Research Board and Campus Fellowship Training Grants)	
☐	**Federal** (from federal agencies, offices, departments, centers)	
☐	**Commercial Sponsorship** (from corporations, partnerships, proprietorships)	
☐	**State of Illinois Department or Agency** (from any state office or entity)	
☐	**Gift or Foundation (including UIF)** (public or private foundations, not-for-profit corporations, private gifts)	

→ Check here if the funding is through a Training Grant: ☐

5C. PROPOSAL A complete copy of the funding proposal or contract is required prior to IRB review. Mark one below:

☐ Attached ☐ Will Follow ☐ Already on File with IRB Office

Sponsor-assigned grant number, if known:

Title of Funding Proposal or Contract, if different from Project Title in Part 2:

5D. FUNDING AGENCY OFFICIAL, IF ANY, TO BE NOTIFIED OF IRB APPROVAL

Last Name:	First Name:	Salutation:	
Agency:	Office Address:	Mail Code:	
Street Address:	City:	State:	Zip Code:
Phone:	Fax:	E-mail:	

6. FINANCIAL INTERESTS: Indicate below if any investigators or any members of their immediate families have any relationships, commitments, or activities with the sponsor of this research that might present or appear to present a conflict of interest with regard to the outcome of the research. (If a financial conflict of interest exists, please submit the UIUC approved conflict management plan. If you have questions about conflict of interest contact the Office of the Vice Chancellor for Research at 217-333-0034.)

☐ Ownership, equity or stock options
☐ Has been disclosed to the UIUC campus **OR** ☐ has not been disclosed to the UIUC campus

☐ Personal compensation such as royalties, consulting fees etc.
☐ Has been disclosed to the UIUC campus **OR** ☐ has not been disclosed to the UIUC campus

☐ Intellectual property such as patents, trademarks, copyright, licensing, etc.
☐ Has been disclosed to the UIUC campus **OR** ☐ has not been disclosed to the UIUC campus

☐ Other conflict of interest:
☐ Has been disclosed to the UIUC campus **OR** ☐ has not been disclosed to the UIUC campus

☒ No conflicts exist

7. SUMMARIZE THE RESEARCH. In **LAY LANGUAGE**, summarize the objectives and significance of the research.

The renewal of the previously used IRB is needed as the research has entered a new phase. The aim of the study and the experiments remains the same however. The objective of the study is to investigate the effect of signal-to-noise ratio (SNR) loss of consonant recognition with hearing impairment. SNR loss is the difference in SNR between normal and hearing impaired listeners required to obtain a score of 50% correct on the Speech-In-Noise (SIN) test. From previous studies, it has been seen that 1) SNR loss cannot be predicted from audiometric measures 2) approximately 40% of hearing aid wearers have 5 dB SNR loss or greater and 3) SNR loss influences speech intelligibility significantly. However, even though these results show the significance of SNR loss for speech perception, they provide little or no information on the nature of the event loss owing to this SNR loss. For this reason, this study aims to 1) compute Fletcher's Articulation Index (AI); which is basically a statistical measure used for predicting speech intelligibility from phones, from the SNR in order to compare predicted and measured scores 2) test a hypothesis that grouping of syllables in terms of consonant confusions for each listener with a given SNR loss, differs from that of normal hearing listeners. The results of the study will provide a detailed understanding of how hearing impaired listeners percieve speech in the presence of noise as a function of SNR loss. This understanding may suggest a means for improving the design of hearing aids to achieve better hearing aid fitting.

If additional information summarizing the Research is attached, check here: ☐

8. PERFORMANCE SITES

Including UIUC sites, describe ALL the research sites for this protocol. For each non-UIUC site, describe: Whether the site has an IRB. Whether the site has granted permission for the research to be conducted. Contact information for the site. If the site has an IRB, whether the site's IRB has approved the research or planned to defer review to a UIUC IRB.		For non-UIUC sites, documentation of IRB approval is:
1.	Beckman Institute #2137, Dept. of Speech Hearing Science #B21,22 UIUC	☐ Attached ☐ Will Follow ☐ N/A
2.		☐ Attached ☐ Will Follow ☐ N/A
3.		☐ Attached ☐ Will Follow ☐ N/A

List and describe any additional Performance Sites information on an attachment and check here: ☐

9. DESCRIBE THE HUMAN SUBJECTS

9A. SECONDARY DATA ONLY? If this research *only* involves the analysis of data that *has already been collected* from human subjects and *no new data collection will occur,* check here: ☐.

9B. MATERIALS OF HUMAN ORIGIN? Will this research involve the collection, analysis, or banking of human biological materials (*e.g.,* cells, tissues, fluids, DNA)? ☐ **Yes** ☒ **No** If yes attach **Appendix C**, the *Biological Materials Form*.

9C. ANTICIPATED NUMBERS How many subjects, including controls, will you study in order to get the data that you need? If you plan to study disproportionate numbers of a given sex, race, or minority group, provide scientific rationale in Part 11.

Performance Site		**# Male**	**# Female**	**Total**
1.	Beckman Institute #2137, Dept. of Speech Hearing Science #B21,22 UIUC	50	50	100
2.				
3.				
TOTALS		50	50	100

List Anticipated Numbers for additional Performance Sites on an attachment and check here: ☐

9D. AGE RANGE Mark all that apply. Researchers planning to include children in research projects involving *more than minimal risk* must provide written documentation of the benefits that are likely to accrue to a child participating in the project. This should include information gathered on adults, if it exists, or an explanation about why it does not exist.

☐ 0–7 years ☐ 8–17 years ☒ 18–64 years ☐ 65+ years

→ ☐ If applicable, written documentation of benefits for including children in ***more than minimal risk*** research is attached.

9E. SPECIAL OR VULNERABLE POPULATIONS Mark groups that will be targeted by design likely to be involved in the research regardless of whether the research targets the group by design.

☒ None of the following special populations will be targeted

☐ Children (age < 18 years)

☐ Neonates
☐ Fetuses *(in utero)*
☐ *in vitro* fertilization subjects
☐ Pregnant or lactating women
☐ Inpatients
☐ Outpatients
☐ Elderly (age > 65 years)
☐ Other (describe here):

☐ Mentally disabled or cognitively impaired persons
☐ Adults with legal guardians
☐ Persons with limited civil freedom (*e.g.,* members of military)
☐ Specific racial or ethnic group(s)— describe:
☐ Low income or economically disadvantaged persons
☐ UIUC Students—name subject pool, if applicable:
☐ Other College Students—name subject pool, if applicable:

9E. If you checked any of the groups in question 9E, describe additional safeguards included in the protocol to protect the rights and welfare of special or vulnerable populations.

If additional Item 9E information is attached, check here: ☐

10. RECRUITMENT

10A. RECRUITING PROCEDURES Specifically describe the systematic procedures for finding and recruiting subjects or requesting pre-existing data or materials. How will voluntary participation be ensured? State whether any of the researchers are associated with the subjects (*e.g.,* subjects are students, employees, patients). Name any specific agencies or institutions that will provide access. Who will contact the prospective subjects? Who gives approval if subjects are chosen from records? Describe solicitation through the use of advertising (*e.g.,* posters, flyers, announcements, newspaper, radio, television, Internet), face-to-face interaction, direct mail or phone contact, classrooms, subject pools, health care registries, patient referrals, and institutional "gatekeepers," as applicable.

Regardless of gender, a total of 100 adults will be selected or recruited using three different procedures. First, possible volunteers will be selected from the database of Speech and Hearing Clinics at UIUC based on characteristics from audiometric records. Subjects will then be recruited by a letter of invitation to participate in this study. Second, subjects will be recruited by using flyers posted in the hearing clinic waiting room and face to face inteactions with patients at the Speech and Hearing Clinics in UIUC by a graduate research assistant. Finally, subjects will be recruited by asking thoses who have already participated in another study that required a similar inclusion and exclusion criteria for subject recruitment.

All participation will be strictly voluntary and follow the signing of the consent form. Subjects will be free to stop participating or withdraw at any time without penalty or prejudice, other than the loss of the financial reward offered for finishing the experiment. All subejcts will demonstrate a documented sensorineural hearing loss, regardless of configuration of the hearing loss. All recruiting processes will be conducted by graduate research assistants.

If additional Item 10A information is attached, check here: ☐

Attach final copies of recruiting materials including the final copy of printed advertisements and the final version of any audio/taped taped advertisements and check here: Attached ☒ Will Follow ☐

10B. WITHHELD INFORMATION Do you propose to withhold information from subjects prior to or during their participation?
☐ Yes ☒ No

If yes, describe what will be withheld, justify the withholding (address risks, provide rationale), describe the debriefing plan, and attach a labeled copy of a written debriefing form, to be provided to subjects. ☐ Debriefing Attached ☐ Will Follow

If additional Item 10B information is attached, check here: ☐

10C. PROTECTED HEALTH INFORMATION (PHI) The IRB must address the privacy and use of health information that is created, received, or housed by health care providers, health plans, or health care clearinghouses and that identifies or could be used to identify an individual. During *either recruiting or data collection*, will you use or have access to such information that is related to the past, present or future health or conditions of a *living or deceased* individual, provision of health care to the individual, or the payment for the provision of health care to the individual? ☐ Yes ☒ No

10D. SCHOOLS-BASED RESEARCH If subjects will be recruited from Illinois public or private elementary or secondary schools, additional deadlines and procedures apply. Criminal background clearances might be required. Special consideration must be given to the exclusion of protected populations. Please contact the Office of School–University Research Relations (OSURR) (217.244.0515 or http://www.ed.uiuc.edu/BER/OSURR.html) for more information. Mark one:

☐ Illinois schools **will** be used ☒ Illinois schools **will not** be used

11. INCLUSION AND EXCLUSION CRITERIA Address all four of the following items in explaining who will and will not qualify for participation and how that determination will be made: (1) Describe procedures to assure equitable selection of subjects. Justify the use of any special or vulnerable groups marked in Part 9E. Selection criteria that target one sex, race, or ethnic group require a clear scientific rationale. (2) List specific criteria for inclusion and exclusion of subjects in the study, including treatment groups and controls. (3) Name and attach copies of measures and protocols that will be used to screen applicants. (4) Explain how the inclusion/exclusion criteria will be assessed and by whom. If special expertise is required to evaluate screening responses or data, tell who will make this evaluation and describe their training and experience.

1) No subject will be eliminated on the basis of gender, race or ethnic group. A total 100 listeners with sensorineural hearing loss will be recruited for the study and the hearing impairment will be evaluated by inspecting the pre-existing audiograms, a graph showing frequency sensitivity of hearing.

2) The study requires adults in the age of 18-64 only.

3) Every individual should be a native Amerian English speaker.

4) Pre-existing patients' audiograms will be used to screen applicants. Only those patients with pure tone average (PTA) ranging from 20 to 80 dB HL will be recruited.

5) The criteria will be assessed by the graduate research assistant running the tests.

If additional Item 11 information is attached, check here: ☐

12. RESEARCH PROCEDURES: Using LAYMAN'S LANGUAGE, specifically describe what the participants (treatment groups and controls) will do and where the research activities will take place. Give approximate dates and durations for specific activities, including the total number of treatments, visits, or meetings required and the total time commitment. Describe the plan for monitoring the data collected to ensure the safety of subjects, if applicable.
(For schools-based research where class time is used, describe in detail the activities planned for nonparticipants and explain where (*e.g.,* in a classroom, in a private area) both participants and nonparticipants will be located during the research activities. Include a concise description of procedures, locations, time commitments, and alternate activities on the relevant consent and assent forms.)

The consonant identification test is administered to measure confusion matrices as a function of SNR. The protocol for the test will involve listening to 16 consonant-vowel or vowel-cosonant syllables recorded by 18 talkers at SNR that decrease in 5 or 10 dB steps, from 25 to -25 dB SNR. The test signals will be presented throught either an Etymotic ER2 insert earphone or a standard circumaural headphone. The participants will be asked to adjust the level of 10 noise free CVs, to the most comfortable listening level. The maximum speech sound presentation level at the output of the insert earphone will not exceed 85 dB (pure tone 1kHz RMS level).
The participant's goal is to identify syllales and pick the target from a graphical user interface. A practice session will be completed in the first 1 hour, or less. The total participation time is estimated to be about 6 additional hours, performed in 3 visits. All testings will be conducted in a sound teated booth, located in the Speech Lab (room #2137) at Beckman Institute.

Procedure for Threshold Equalized Noise (TEN) tests: The absolute pure tone and noise masked thresholds in the test are measured using standard clinical procedures of audiometry (Carhart and Jerger). Masker levels are set to 70 dB/ERB. The stimuli are delivered using the Etymotic ER2 insert earphone. Each ear is tested reparately.

Procedure for measuring Puretone Tuning Curve (PTC): The signal is a sinusoid which is presented at a level 10 dB above the absolute threshold. In a given run, the signal frequency is fixed. The masker is an 80 Hz narrow-band of noise with variable centre frequency. The exact masker frequencies are chosen individually for each subject, so as to define the position of the tip of the tuning curve with reasonable accuracy. Several siginal frequencies are used for eacg subject to cover a range, including the susepcted dead regions.

Procedure for measuring Comodulation Masking Release (CMR): Participants will continuously hear three brief pure-tone sounds at the testing frequency through Etymotic ER-2 insert earphone and then simply say one different sound among three. Loudness of sound starts at the most comfortable and/or loud enough level based on the outputs ofaudiogram and is decreased by 5 dB step-size like a typical clinical audiometric procedure. The softest level will be decided as CMR threshold of each participant. Testing frequency will be chosen from 500 Hz to 8000 Hz. It will take less than 15 minutes at each testing frequency.

If additional Procedures are attached, check here: ☐

13. EQUIPMENT Will any physical stimulation or physiological data acquisition equipment be used with the subjects?
☐ Yes ☒ No If yes, attach **Appendix A**, the *Research Equipment Form*.

14. DRUGS, DEVICES, AND BIOLOGICS Will any drugs, devices, or chemical or biological agents be used with the subjects?

☐ Yes ☒ No If yes, attach **Appendix B**, the *Drugs, Agents, and Devices Form*.

15. MRI AT BIC To use the Beckman Institute Biomedical Imaging Center (BIC) in human subject's research, you must obtain *prior approval* from the BIC (217.244.0600; bmrf@bmrl.bmrf.uiuc.edu) and use BIC-approved screening and consent forms. Attach:

BIC approval	☐ Attached
BIC screening form	☐ Attached
BIC consent form	☐ Attached

16. MEASURES If subjects will complete questionnaires, surveys, interviews, psychological measures, or other measures, however administered, the IRB must review and approve the measures. List all such measures here and attach complete, labeled copies (including translations, if applicable) to this application:

Measure 1:	Any auditory event(s) after their last hearing test	☐ Attached	☐ Will Follow
Measure 2:		☐ Attached	☐ Will Follow
Measure 3:		☐ Attached	☐ Will Follow
Measure 4:		☐ Attached	☐ Will Follow

List additional Measures on an attachment and check here: ☐

17. SUBJECT REMUNERATION

Will subjects receive inducements or rewards before, during, or after participation? ☒ Yes ☐ No

If yes, will payment be prorated for partial participation? ☒ Yes ☐ No

If remuneration will be given, for each subject group:

(1) specify the form of remuneration, including $, course credit, lottery, gift certificate, or other;
(2) state the $ amount or the approximate $US value, or the course credit and its percentage of the final grade;
(3) explain the remuneration plan, including whether and how prorating will be made for partial participation;
(4) for lotteries, include (a) the number of prizes, (b) the nature and value of each prize, (c) the approximate odds of winning, (d) the date(s) of the drawing(s), and (e) how winners will be notified, by whom, and by when; and
(5) include all this information on the relevant consent forms.

Participants will be compensated on a pro-rated basis on $10 per hour. If participants choose to withdraw from the study, they will receive partial compensation for the time that they have participated for.

If additional Subject Remuneration information is attached, check here: ☐

18. SUBJECT OUTLAY Will subjects incur costs for research-related procedures (*e.g.*, longer hospitalization, extra tests), use of equipment, lost compensation, or transportation (over 50 miles)? ☐ Yes ☒ No If yes, describe here:

If additional Subject Outlay information is attached, check here: ☐

19. CONFIDENTIALITY OF DATA Answer each of the following to describe methods that will ensure the confidentiality of individually identifiable data. Confidentiality is required unless subjects give express, written permission to have their identifiable information published, presented, or shared.

19A. CHECK IF USED IN DATA COLLECTION: ☐ Audio tapes/ Digital voice ☐ Video tapes ☐ Still photos ☐ Other imaging

19B. DATA COLLECTION Explain how the data will be collected. If anonymous data collection is proposed, provide details of how investigators *will not have the ability to trace responses to subject identities.* For multiphase data collection or if multiple contacts will be made with subjects, specifically explain the subject tracking and coding systems.

Address the confidentiality of data collected via e-mail, databases, Web interfaces, computer servers, and other networked information, as applicable.

The participants will be identified by their initials and an associated code number on all the response sheets. All response sheets will be kept in files that are accesible to project staffs only. All other paper and computer files will identify subjects by code number only.

The only purpose of email correspondence with the participants will be to schedule a visit to the lab. Subsequent visits wil be scheduled a the end of each session.

If additional Item 19B information is attached, check here: ☐

19C. DATA SECURITY Describe how and where the data be kept so that the data remain confidential.

All response sheets will be kept in files that are accesible to project staffs only. All other paper and computer files will identify subjects by code number only.

If additional Item 19C information is attached, check here: ☐

19D. STAFF TRAINING Describe the training and experience of all persons who will collect or have access to the data.

Persons associated with running the study will be graduate students in deparments of ECE and SHS. Training will involve familarization with the equipment and the protocol, observing the principle invesigator conducting the tests under supervision. A graduate reseach assistant will have at least two hours of training prior to independent data collection and will also have acted as a subject in the experiment for at least two hours. Moreoever, all graduate reseach assistants (research investigators) including the RPI have also completed the UIUC IRB training module sucessfully.

If additional Item 19D information is attached, check here: ☐

19E. DATA RETENTION How long will the data be kept?

5 years

If additional Item 19E information is attached, check here: ☐

19F. DISSEMINATION OF RESULTS What is(are) the proposed form(s) of dissemination (*e.g.,* journal article, thesis or academic paper, conference presentation, sharing within industry or profession)?

Journal articles, conference presentation, and sharing with people in the profession

If additional Item 19F information is attached, check here: ☐

19G. PRIVACY Describe provisions to protect the privacy interests of subjects.

The experiment will be conducted in a sound treated booth at the Speech Lab #2137 at Beckman Institute. All response sheets will be kept in files that are accesible to project staffs only. All other paper and computer files will identify subjects by code number only. The only purpose of email correspondence with the participants will be to schedule a visit to the lab.

If additional Item 19G information is attached, check here: ☐

19H. INDIVIDUALLY IDENTIFIABLE INFORMATION Will any individually identifiable information, including images of subjects, be published, shared, or otherwise disseminated? ☐ Yes ☒ No

If yes, subjects must provide explicit consent or assent for such dissemination. Provide appropriate options on the relevant consent documents.

20. INFORMED CONSENT Describe the procedures for obtaining voluntary informed consent and attach consent documents that contain the federally required elements. **Federal regulations and University policy require the execution of a comprehensive, written document that is signed by the subject (or the subject's authorized representative) as the principal method for obtaining consent from subjects. The language in the document must be understandable to the subject or the subject's legally authorized representative.** A Waiver or Alteration of Informed Consent or a Waiver of Documentation (signature) of Informed Consent (e.g., online consent, oral consent) may be approved by the IRB. If requesting a waiver please complete the appropriate waiver form at: www.irb.uiuc.edu and submit it with the IRB Application for review.

Children must *assent* (or, voluntarily agree) to participation and a parent must separately consent on behalf of their child (*i.e.,* two different forms are generally required). Children under age 8 may assent either orally or passively, depending on their level of maturity. Children 8–17 years old should sign a written form unless the UIUC IRB approves a different process. Describe the assent process in Section 20 D.

20A. TYPE OF CONSENT Check all that apply and attach one copy of each relevant form, letter, or script on university letterhead. Include translations, if consent will be obtained in a foreign language. Use headings, headers, or footers to uniquely identify each document and associate it with the subject group for which it will be used.

☒ **Written informed consent (assent) with a document signed by**
☒ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years

☐ **Waiver or Alteration of Informed Consent (Attach waiver form.)**
☐ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years

☐ **Waiver of Documentation (signature) of Informed Consent (Attach waiver form.)**
☐ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years

20B. USE OF PROXY Will others (*e.g.,* next of kin, legal guardians, powers of attorney) act on behalf of adult subjects in giving consent to participate in this research? ☐ Yes ☒ No if yes, describe in Section 20D.

20C. USE OF PROXY OUTSIDE THE UNITED STATES If a proxy is used in research conducted outside Illinois, provide justification (e.g., statement of an attorney or copy of applicable law) that the proxy is authorized under the laws of the jurisdiction in which the research will be conducted to consent to the procedures involved in this protocol.

20D. CONSENT PROCESS Describe when and where voluntary consent will be obtained, how often, by whom, and from whom. If cognitively impaired subjects (including children under age 8) will be involved, explain how the subject's understanding will be assessed and how often; include the questions that will be asked or actions that will be taken to assess understanding.

Describe any waiting period between informing the prospective subject and obtaining the consent. Describe steps taken to minimize the possibility of coercion or undue influence. Indicate the language used by those obtaining consent. Indicate the language understood by the prospective subject or the legally authorized representative.

If the research involves pregnant women, fetuses, or neonates, indicate whether consent will be obtained from the mother, father, or both. If the research involves children, indicate whether consent will be obtained from: Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; or from one parent regardless of the status of the other parent.

Voluntary consent will be obtained from the participants during the initial visit to the lab before commencing any of the experiments. It will be obtained by a trained graduate research assistant ot the RPI.
Consent obtained will be valid for a total 3 testing sessions, each session lasting two hours including breaks. For an individual, all testings will be completed within one month of the initial visit.

If additional Item 20D information is attached, check here: ☐

21. RISKS

21A. DESCRIPTION Specifically describe all known risks to the subjects for the activities proposed and describe the steps that will be taken to minimize the risks. Include any risks to the subject's physical well-being, privacy, dignity, self-respect, psyche, emotions, reputation, employability, and criminal and legal status. Risks must be described on consent forms.

The only risk in the study is that of presenting loud sounds to the subjects. We will avoid this by electrically limiting the maximum level that the system can produce to a safe listening level using a fixed attenuator. As an additional precaution each subject will be instructed to stop the test if the sound level is too loud and inform the investigator. In this manner, the risk of exposure to loud sounds can be made within reasonable limits.

If additional Risks information is attached, check here: ☐

21B. RISK LEVEL: ☒ **No more than minimal risk**
(the probability and magnitude of harm or discomfort anticipated for participation in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

☐ **More than minimal risk**

21C. If you checked that the research is more than minimal risk, describe the provisions for monitoring the data to ensure the safety of subjects (Who will periodically monitor harms and benefits experienced by subjects to ensure that the relationship of risks to potential benefits remains unchanged? How often will monitoring occur? What analyses will be performed? If appropriate, what criteria will be used to stop the research based on monitoring of the results?)

22. BENEFITS Describe the expected benefits of the research to the subjects and/or to society.

Participants will benefit by knowing their ability to hear in noise. Society and the field of hearing science will benefit from the findings that will improve the understanding of speech perception in noise for people with hearing impairement. The results should ultimately lead to means of designing better hearing aids.

If additional Benefits information is attached, check here: ☐

23. RISK/BENEFIT ASSESSMENT Weigh the risks with regard to the benefits. Provide evidence that benefits outweigh risks.

The risks associated with this study are negligible. The procedures are comparable to routine clinical hearing tests. All subjects are also encouraged to take a break after every 20 minutes to avoid fatigue and boredom.

If additional Risk/Benefit information is attached, check here: ☐

24. Is this a multi-center study in which the UIUC investigator is the lead investigator of a multicenter study, or the UIUC is the lead site in a multi-center study. **Yes** ☐ **No**☒

If yes, describe the management and communication of information obtained that might be relevant to the protection of subjects, such as: Unanticipated problems involving risks to subjects or others. Interim results. Protocol modifications.

25. INVESTIGATOR ASSURANCES: The original signature of the Responsible Project Investigator is required before this application can be processed (scanned or faxed signatures are acceptable). Other investigators are also responsible for these assurances and are encouraged to sign. Neither stamps nor proxy signatures are accepted in this section.

I certify that the information provided in this application, and in all attachments, is complete and correct.

I understand that I have ultimate responsibility for the protection of the rights and welfare of human subjects, the conduct of this study, and the ethical performance of this project.

I agree to comply with all UIUC policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects in research.

I certify that

- the project will be performed by qualified personnel according to the UIUC IRB-approved protocol.
- the equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
- no change will be made to the human subjects protocol or consent form(s) until approved by the UIUC IRB.
- legally effective informed consent or assent will be obtained from human subjects as required.
- Unanticipated problems, adverse events, and new information that may affect the risk–benefit assessment for this research will be reported to the UIUC IRB Office (217.333.2670; irb@uiuc.edu) and to my Departmental Executive Officer.
- I am familiar with the latest edition of the UIUC *Handbook for Investigators*, available at www.irb.uiuc.edu, and I will adhere to the policies and procedures explained therein.
- student and guest investigators on this project are knowledgeable about the regulations and policies governing this research.
- I agree to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.
- if I will be unavailable, as when on sabbatical or other leave, including vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence. I will advise the UIUC IRB by letter of such arrangements.

I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.

NOTE: The original signature of the RPI must be submitted before IRB Review (scanned or faxed signatures are acceptable)**.**

Responsible Principal Investigator	Date	Investigator	Date

Investigator	Date	Investigator	Date

25. (OPTIONAL) DEPARTMENTAL ASSURANCE To be completed by the RPI's Departmental Executive Officer or their designee (proxy and stamped signatures are acceptable).

The activity described herein is in conformity with the standards set by our department and I assure that the principal investigator has met all departmental requirements for review and approval of this research.

Departmental Executive Officer (or designee)	Date

Beckman Institute and the Department of Electrical and Computer Engineering
University of Illinois at Urbana-Champaign
Telephone: (217) 333-2300

INFORMED CONSENT
Speech Perception Hearing Test

I agree to participate in a research study conducted by Jont Allen, Ph.D. of the Department of Electrical and Computer Engineering. The purpose of the study is to investigate the effect of signal-to-noise ratio (SNR) loss on confusion of consonant recognition in hearing impairment.

Eligibility requires participants: (a) to be 18 to 64 years of age, (b) to have sensorineural hearing loss on the basis of a standard hearing test, (c) to have the ability to perform a mouse-click in response to detection of short speech syllables, and (d) to be a native American English speaker.

You will be asked to report your age and history of hearing health and have your hearing tested if necessary. The study involves a series of tests of hearing for speech in noise. You will listen to short speech sounds presented in a noisy background and identify each after it is presented by using a computer mouse to select that sound from a list shown on a computer monitor. The sound levels will be slightly higher than that of conversational speech or the most comfortable loudness level.

Total testing time will take less than 9 hours. It will be divided by 3~4 sessions depending on your preference and available time. Most testing will be conducted in room #2137 Beckman Institute, except for hearing screening at Department of Speech and Hearing Science (#B21 and #B22). You will benefit by knowing your ability (SNR loss) to hear in noise. In return for your participation, you will be paid $10/hour.

There are no physical risks associated with this study other than those encountered in normal daily life. Rest breaks will be given, as needed. The information that you release will be kept confidentially. Your information will be assigned a code number. The list connecting your name will be kept in a locked file cabinet. Your name will not be used in any report.

Participation in this study is completely voluntary. There is no penalty for not participating. You have the right to withdraw at any time without penalty. Questions can be addressed to: Prof. Jont Allen, Principal Investigator, Electrical & Computer Engineering Department, 2061 Beckman Institute (217-244-9567; jontalle@illinois.edu) or to the *graduate student administering the test*. Subjects can also contact the *IRB Office* (217-333-2670; irb@illinois.edu) for information about the rights of human subjects in UIUC-approved research. If you live outside the local calling area, invite to call the researchers collect and the IRB collect. You will be given a copy of the consent form.

I certify that I have read this form and volunteer to participate in this research study.

Signature of Participant Date

Signature of Witness Date

Example of invitation letter

Dear

You are invited to participate in a research study designed to help identify how hearing loss affects the ability to understand speech in noise. The study involves identifying short speech sounds and short sentences in the background noise.

The study involves a series of tests of hearing for speech in noise. You will listen to short speech sounds presented in a noisy background and identify each after it is presented by using a computer mouse to select that sound from a list shown on a computer monitor (consonant identification task). In the first visit we will perform a brief hearing screening test and provide you with practice in consonant identification tasks. Then you will perform the first portion of test. In the next two visits you will complete the test.

The research will be conducted in the Speech Lab (room #2137) at Beckman Institute, the University of Illinois at Urbana-Champaign, except for the hearing screening test (at Speech and Hearing Clinic). You will receive a payment of $10/ hour. Parking fees will be reimbursed. The study should take approximately 8~10 hours over three visits (but, we can adjust the experiment time and visiting time with your convenience).

There are no physical risks associated with this study other than those encountered in normal daily life. Rest breaks will be given, as needed. Participation in this study is completely voluntary. You are free to ask questions and to withdraw at any time without penalty or loss of rights to which you are entitled. Your participation in this study will be confidential.

Thank you for your consideration of participation in this study.

To set up an appointment or to ask questions about the research project, please contact graduate research assistants; Woojae Han: (217) 417-1378 or *whan5@illinois.edu*