Purdue IRB Protocol #: 1609018209 - Expires: 27-OCT-2021

RESEARCH PARTICIPANT CONSENT FORM Human Sensory Processing of Complex Scenes Hari Bharadwaj, Ph.D. Department of Speech, Language, and Hearing Sciences Purdue University

Key Information

Please take time to review this information carefully. This is a research study. Your participation in this study is voluntary which means that you may choose not to participate at any time without penalty or loss of benefits to which you are otherwise entitled. You may ask questions to the researchers about the study whenever you would like. If you decide to take part in the study, you will be asked to sign this form, be sure you understand what you will do and any possible risks or benefits.

The purpose of this study is to better understand how our ears and brains help us communicate in noisy environments such as crowded restaurants and busy streets. Each session you participate in will be scheduled for not more than 4 hours including breaks, although most visits will take less time than that. We expect that the set of tests will take 3-4 visits to our facilities at Purdue University.

The person in charge of this study is Hari Bharadwaj. Prof. Bharadwaj can be reached at hbharadwaj@purdue.edu (765-496-2249). We will refer to this person as the "principal investigator" throughout this form. The individuals working on this study on behalf of the principal investigator will be referred to as the "researchers" throughout this form.

What is the purpose of this study?

The purpose of this study is to better understand how our ears and brains help us perceive the world around us. In particular, we are interested in understanding how our senses allow us to have conversations in complex environments such as crowded restaurants and busy streets.

What will I do if I choose to be in this study?

If you agree to take part in this study, we will ask you to sign this informed consent document before we do any study procedures. After signing this consent document, we will perform the procedures indicated below. First, a basic hearing profile measurement will be conducted. This procedure evaluates whether you meet our screening criteria for normal hearing, if applicable. Once we establish that you meet the screening criteria, the remaining procedures described in this document will be performed. These procedures may be done on the same day, or may be spread out over different days. Each visit to the lab will be scheduled for not more than 4 hours including breaks, although most visits will take less time than that. We will compensate you for your time as indicated in the "Will I receive payment or other incentive section" below.

Screening:

We are seeking your consent for the study because you expressed interest by responding to one of our flyers. You have indicated that you have no known neurological problems, and have [researcher will circle one]:

Normal hearing in quiet places [OR] Hearing loss

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For this study we define normal hearing and mild hearing loss based on your ability to detect faint sounds. We will use measurements in a quiet booth to assess this ability. For this procedure, you will be asked to wear an earphone/headphone and we will play sounds such as beeps and clicks and ask you to respond whenever you hear the sounds. Your responses will be used to identify the faintest sounds you can hear at different pitches. Normal hearing, for this study, means that you are able to detect sounds within 25 dB HL. For our experiments involving individuals with normal hearing, eligibility to continue to the other parts of this study requires that you meet these criteria. These screening measurements remain valid for 6 months and will be repeated if your completion of any parts of the study extends beyond that period (this is unlikely).

Once you pass the screening procedures listed above, you will proceed to complete other parts of the study. In the event that you do not meet the eligibility criteria, you will be compensated for the time spent for the consent and screening procedures.

Note that while our screening measurements may resemble tests that are performed in audiology clinics, we emphasize that our data is for research purposes only. We are not health professionals or not acting in that capacity, and therefore cannot make a diagnosis as to your hearing status. In case you do not meet our eligibility criteria, we will provide documentation of our measurement. You may choose to follow up with your own health care provider.

Participant's initials:	
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The following procedures will only be performed after you pass the screening procedure described above.

Questionnaires: We will request that you fill out responses to questionnaires. This may include information about your musical ability, your history of exposure to loud sounds, demographic information, handedness (i.e., right handed or left handed), etc.

Supplementary Hearing Profile: We will use additional measurements in a quiet booth to assess your hearing profile. For these procedures, you will be asked to wear a regular earphone/headphone, or one of three special headsets that either (i) gently vibrate the bone behind your ear, or (ii) have an extra microphone to measure sounds from in your ear, or (iii) mildly pressurize your ear. These headsets should all feel similar to wearing an earphone or headphone but may look different. Using these headsets, we will play sounds such as beeps and clicks. You may be asked to respond with a button press or a verbal/gestural indication, or sit quietly. For example, we may play faint beeps and ask if you to press a button or raise your hand whenever you hear it.

In addition, we will perform the tests indicated by the checked boxes below:

☐ Computer-based tasks: For these tests, you will be seated in a quiet booth and complete tasks on a computer. You may or may not need to wear headphones for these tasks. You may listen to sounds of different types (such as beeps or speech) and/or be presented with images and be asked to answer questions about what you heard and/or saw. For example, "did the sound jump from left to right, or right to left?". You will answer by pressing a key, or selecting a IRB No. 1609018209

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choice on a touch screen, or clicking on an item using a mouse. These computer tasks may be done during one session or over multiple sessions. ☐ EEG (electroencephalogram): An EEG is a test that measures and records the electrical activity of your brain. We will record your EEG by placing sensors embedded in a cap - similar to a swimming cap - on your head. Your head circumference will be measured to select the suitable cap size for you, the cap will be placed on your head, and the holes in the cap will be filled with gel. Up to eight additional sensors will be placed on your face and at the back of your ears. Some cleaning of the skin with an alcohol wipe may be required. Once the cap is setup on your head, you will be seated in a quiet booth. Some audio and/or visual stimuli will be presented to you while you are wearing the cap. You may be asked to perform a computer task, or you may be asked to sit quietly. If you are asked to sit quietly, the researcher will instruct you on how to pass the time (e.g., watching a silent movie with subtitles). EEG may be done within one session or over multiple sessions. ☐ Environmental sound level recorder: You will be given a small device to take home with you and wear on your shoulder (clip on to shirt). This device registers how loud the environments are that you happen to find yourself in as part of your day-to-day activities (e.g., restaurants, music practice). Although this device is similar to a simple sound recorder, it does not record the sounds themselves; it only measures how loud they are. The researcher will demonstrate how to wear the device and when and how long to wear it (for a few hours per day over 3-5 days of typical everyday activity) and how to return it. This measurement helps us understand how the levels of sounds you are exposed to from day-to-day activities influences how your ears and brain process sound information. You are not responsible for the loss or damage of this device. While some of our measurements may resemble tests that are performed in audiology clinics or in diagnostic imaging, we emphasize that our data is for research purposes only. Thus we are not looking for patterns that would suggest a hearing or neurological problem, and we may not find them even if they are present in our measurements. Neither the principal investigator nor the researchers are health professionals, and therefore cannot make a diagnosis as to your hearing or neurological status. Participant's initials: How long will I be in the study? Each visit to the lab will be scheduled for not more than 4 hours including breaks, although most visits will take less time than that. We expect that the set of tests will take 3-4 visits to Purdue University. Scheduling of visits will be done based on your availability. Depending on the length of each visit, and for technical reasons (if we have issues related to data quality in some of the visits), we may request that you participate in follow-up measurements or additional visits. Note that participation in any experiment is voluntary and that you may withdraw at anytime, including partway through a session. If you are willing, we would like to be able to contact you when we conduct studies in the future. Are you are interested in being contacted about future studies? YES / NO.

If yes, please initial below.

Participant's initials:

What are the possible risks or discomforts?

Our measures are non-invasive; thus the potential risks are minimal, i.e., no more than day-to-day activities or a routine doctor visit.

<u>Risk from sounds:</u> Because we are playing sounds, one possible risk is that you may hear sounds that are too loud for comfort. This is unlikely because we carefully calibrate our sounds. If any sounds are uncomfortable, please remove the earphones and let the researcher know. In the unlikely event that you experience such an exposure briefly, there is little risk of any long-term or serious harm.

<u>EEG risks:</u> Another possible risk is the potential for mild discomfort from electrodes being attached to your scalp and skin. Our EEG equipment only requires minimal skin cleaning. The gel we use will wash off easily. Additionally, we disinfect our caps and electrodes after each use and use disposable equipment when applicable. So the risks of skin irritations are minimal. If you experience any discomfort, please let the researcher know.

<u>Breach of confidentiality:</u> Because no security system is perfect, there is the unlikely possibility of breach of confidentiality of the information you provide to us. Safeguards to minimize this risk are in place and are discussed in the confidentiality section of this form.

Are there any potential benefits?

There are no direct benefits for you. We anticipate that the information gained from this research will help us understand better how our hearing and brains work. This may lead to benefits to society at large, such as through improved diagnostics, better hearing aids, etc.

Will I receive payment or other incentive?

You will be compensated for the time you spend with us participating in the study. Payment will be at the rate of \$16.00 per hour for the entire time, i.e., from when you arrive at the lab till you leave. Time spent will be calculated in 15-minute increments rounded up.

In the event that you withdraw your participation partway through the study, you will be compensated for the time you have spent up to that point. You will be paid a bonus amount at the end of the whole study if you complete all sessions. This "completion bonus" is on top of the usual per-hour payment and will only be paid in the event of completing all parts of the study. The bonus amount is a flat \$16.00.

Will information about me and my participation be kept confidential?

Your identity will be kept confidential. Any identifying information we collect (e.g., this form) will be stored in the principal investigator's office or laboratory, which are kept locked. Only the researchers conducting this study will have access to any identifying information. Reports and scientific publications will *not* contain any identifying information. Information and recordings from this study may be used for future research and may be kept indefinitely. If any measurements are shared with researchers outside our team (e.g., collaborators), identifying information will be completely stripped before sharing.

In order to process payments, the business office of the Department of Speech, Language and Hearing Sciences requires certain information. This includes your typed/printed name and signature on a form. Your name, social security number and address may also be required to process your payment. Thus, personnel at the business office may see this information in connection with your participation in this experiment. The project's research records may also be reviewed by departments at Purdue University responsible for regulatory and research

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oversight. Finally, should the National Institutes of Health (NIH) or other agencies award us funding for the study, then they may review the research records.

What are my rights if I take part in this study?

Your participation in this study is voluntary. You may choose not to participate or, if you agree to participate, you can withdraw your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Who can I contact if I have questions about the study?

If you have questions, comments or concerns about this research project, you can talk to one of the researchers, or contact the principal investigator Prof. Hari Bharadwaj at hbharadwaj@purdue.edu or (765) 496-2249.

If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email (irb@purdue.edu) or write to:

Human Research Protection Program - Purdue University Ernest C. Young Hall, Room 1032

155 S. Grant St., West Lafayette, IN 47907-2114

Documentation of Informed Consent

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research study, and my questions have been answered. I am prepared to participate in the research study described above. I will be offered a copy of this consent form after I sign it.

Participant's Signature	Date
Participant's Name (Please use capital letters)	
Researcher's Signature	 Date