Official Title: Peripheral and Central Contributions to Auditory Temporal Processing Deficits and Speech Understanding in Older Cochlear Implantees

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Institutional Review Board
1204 Marie Mount Hall ● 7814 Regents Drive ● College Park, MD 20742 ● 301-405-4212 ● irb@umd.edu

CONSENT TO PARTICIPATE

Project Title	Peripheral and central contributions to auditory temporal processing deficits and speech understanding in older cochlear implantees: Cochlear Implant Participants
Purpose of the Study	This research is being conducted by **Matthew Goupell** at the University of Maryland, College Park. We are inviting you to participate in this research project because you have a cochlear implant in one or both of your ears. The purpose of this research is to learn how people with cochlear implants hear sounds and understand speech. People with cochlear implants tend to struggle to understand speech, particularly in difficult environments like background noise. We are seeking information on how the brain processes sounds from the cochlear implant(s) to improve how the devices work.
Procedures	The procedures involve one or more of the following: 1) Listening to electrically pulsed signals to determine loudness levels and auditory nerve response via a clinical mapping setup (similar to what occurs at the audiologist). 2) Listening to simple electrically pulsed signals to determine the loudness levels of your implant via direct stimulation that connects your implant directly to a computer. 3) Listening to a range of simple to complex electrically pulsed signals via direct stimulation. 4) Listening to sounds and speech over headphones or loudspeakers in a quiet room via your processors. 5) Listening to sounds and speech over the direct audio input to your processors. 6) Listening to sounds and speech on research processors, which work similarly to your own processors. 7) Listening to and/or reading sentences, words, or numbers. 8) A basic vision test. 9) Watching videos of people speaking both with and without sound. 10) Measurement of small electrical responses from the surface of your head and skin that reflect brain waves specific to hearing. 11) Providing CT (computed tomography) scans of your head (if previously taken) or taking CT scans of your head to define the position of your cochlear implant(s) in the cochlea. 12) Answering questions and following simple instructions that are designed to measure memory and attention. 13) Listening to sounds and speech while seated at an eye tracker. The eye tracker is a remote camera that measures where you are

	looking and your pupil size across time. This measurement is made while you rest your head on a chin rest and/or forehead bar. For the above procedures, you will respond to differences in sounds or report the speech that you heard, usually with a computer keyboard, mouse, or with a spoken response. You may be asked to remember and/or order words, sentences, or numbers that you just heard. Your speech when repeating words and sentences may be audio-recorded for scoring. You may choose to not have your voice recorded and to not take part in that part of this study. Most of these tasks are auditory. Some are not. The purpose of the non-auditory tests is to examine skills like memory, processing speed, and attention. You do not need to take part in all tasks and may choose to only complete some parts of the study. Not all participants will be invited to complete all parts of the study. These procedures typically take several days (not necessarily consecutive), depending on your schedule and availability. The listening tests are usually given in blocks of approximately 20 minutes, with frequent breaks between blocks and breaks for lunch. You may be asked if you would be willing to continue for an additional time, depending on the experiment. There will be no pressure on you to continue if you want to stop. If you participate in the electrophysiological testing, you will sit in a reclining chair. Standard silver-silver chloride electrodes will be placed on your head with electrode paste. You will watch movies on DVD. You will hear speech or other sounds delivered over the direct audio input to your processors, via direct stimulation that bypasses your processor (i.e., connecting your implant directly to a computer), or on research processors, which function similarly to your own processors. The electrodes will measure auditory evoked potentials, which are brain waves specific to hearing. The electrophysiological testing will take 2-5 hours and may occur over multiple days depending on your preference. You may stop at any time. If you participate in the CT part of this study, the CT scan will be performed in the radiology department at Georgetown University Medical Center. If you are receiving a CT scan, you will first participate in a clinical visit with a Georgetown otolaryngologist. To schedule an appointment at Georgetown University, you need to be registered there as a patient and we would need to request some additional information from you prior to your visit. This information

	will include your name, date of birth, sex, marital status, race, ethnicity, employment status, preferred language, primary phone address and email address. This information will be used only to schedule an appointment at Georgetown University Medical Center and will not be used for research purposes. During your visit to the otolaryngologist, he/she will request certain medical information which will become part of your clinical record, but will not be used for research purposes. This information may include: hearing loss history, dizziness history, ear-related medical history, such as earaches, ear discharge, history of ear infections, past medical and surgical history, social & family history, medications, allergies, a focused ear exam, and head and neck exam. The CT-visit will take between 1 to 4 hours depending on scheduling. If you are a female of child bearing potential, a urine or blood pregnancy test will be done before the CT scan. If you are pregnant you cannot participate in the CT portion of the study. If you have already had a CT scan of your head done, it may not need to be done again. We would only ask to obtain a copy of your scan results to use the results in this study. You can choose not to participate in the CT scan part of the protocol and still be eligible to participate in other parts of this study. All procedures (except for any CT scans) will be conducted in the Hearing and Speech Sciences Department at the University of Maryland at College Park, in quiet rooms like a sound booth or sound-treated chamber.
Potential Risks and Discomforts	There may be some risks from participating in this research study. The tests can be repetitive and boring for some people. You will be allowed frequent breaks to reduce boredom, fatigue, or discomfort from sitting or standing during our tests. You will be asked to listen to sounds presented either over the headphones or from loudspeakers in quiet rooms. The sounds are always presented at comfortable loudness levels, and will never intentionally be uncomfortably loud or unsafe. You may be asked to listen to sounds through direct electrical stimulation, when we connect your implant directly to a computer. This procedure is similar and presents no greater risk than a mapping procedure at your appointment with an audiologist. There is the small possibility that overstimulation and an uncomfortably loud sound will be presented, which would cause slight discomfort and possible twitching of the facial muscle. In the unlikely event that one of these events occurs, we will stop testing immediately and resume only if you wish. At any time you can take the magnetic coil off your head to stop the sounds.

	On rare occasions, some people experience minor, temporary skin irritation from the electrode paste. This can be reduced by washing with water. If you participate in the CT scan portion of the study, this will involve exposure to radiation from the CT scanner. The amount of radiation exposure that you will receive is about equal to the exposure that you would receive from natural background sources over a period of 7 months. Also, if you participate in the CT scan portion of the study and you are a female of childbearing potential you will have a pregnancy test done to see if you are pregnant. If this test is done using blood: pain, redness, soreness, bruising, or infection may occur at the needle stick site. Rarely some people faint. If eye tracking is completed, there is additional risk of discomfort from having one's head still in a chin rest and/or forehead bar during testing. Frequent breaks will be provided. Eye trackers employ a low level of infrared light to track pupil size and position. The amount of infrared light exposure is less than 7.5% of the maximum allowable exposure and comparable to the amount of exposure experienced on a bright, sunny day. As in all research studies, there is the potential risk for the loss/breach of confidentiality. These risks will be reduced using the measures described below in the Confidentiality section.
Potential Benefits	This research is not designed to help you personally, but the results may help the investigator learn more about how the auditory system functions, and might in the future help us to improve the design of hearing aids and cochlear implants.
Confidentiality	Any potential loss of confidentiality will be minimized by assigning a participant code to your information and storing your data in a locked office and on password protected computers. The identification key between your real name and your code will be kept in a different location to the data, and can only be accessed by the researcher. This research will probably be published in a scientific journal, but will not contain any material that will identify you as a participant. Records are kept at least 7 years past the time of publication of the results in peer-reviewed journals as per NIH policy, and likely longer. When the data are no longer needed, any paper with identifiable information will be shredded through a university-approved shredding service and all digital files will be deleted. If we write a report or article about this research project, your identity will be protected to the maximum extent possible. Your information may be shared with representatives of the University of Maryland, College Park, Georgetown University, Georgetown University Institutional Review Board (IRB), or governmental authorities if you or someone else is in danger or if we are required to do so by law.

Medical Treatment	Should you get a CT scan (Procedure item 11), the research team will cover the costs of the visit. Your insurance will not be billed. The Policy and Procedure for Georgetown University Medical Center are as follows: We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care at the usual charge. The costs of this care will be charged to you or your health insurer. No funds have been set aside by Georgetown University, Georgetown University Hospital, MedStarHealth Research Institute, or their affiliates, to repay you or compensate you for a study related injury or illness.
Compensation	For your part in this study, you will be paid as a Research Participant according to a predetermined pay scale of $25 per hour (for less than 6 hours of testing in a day) or $150 for each 6-hour testing day completed. For subjects who do not live in the DC Metro area, the cost of airline tickets and hotel room has been pre-paid by our lab. You and your travel companion will receive reimbursement for travel expenses such as taxi fare to or from the airport or baggage check fees, when you provide receipts. You and your travel companion will also receive reimbursement for the cost of meals at the current per diem rate, about $45 per person per day. If you have driven your own vehicle to College Park, you will be reimbursed mileage at a rate of 62.5 cents per mile with a maximum limit of the cost of airfare from your home airport, or $25. You will be responsible for any taxes assessed on the compensation. If you will earn $100 or more as a research participant in this study, you must provide your name, address and SSN to receive compensation. If you do not earn over $100 only your name and address will be collected to receive compensation.
Right to Withdraw and Questions	Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify. Circumstances that the researcher may terminate subject participation for include: 1) Having a hearing loss or hearing asymmetry that does not meet

	the requirements of the study 2) Inability to keep scheduled appointments If you are an employee or student, your employment status or academic standing at UMD will not be affected by your participation or non-participation in this study. If you decide to stop taking part in the study, if you have questions, concerns, or complaints, or if you need to report an injury related to the research, please contact the investigator: **Matthew Goupell** **0241 Lefrak Hall** **E-mail: goupell@umd.edu** **Telephone: 301-405-8552**
Participant Rights	If you have questions about your rights as a research participant or wish to report a research-related injury, please contact: University of Maryland College Park Institutional Review Board Office 1204 Marie Mount Hall College Park, Maryland, 20742 E-mail: irb@umd.edu Telephone: 301-405-0678 For more information regarding participant rights, please visit: https://research.umd.edu/research-resources/research-compliance/institutional-review-board-irb/research-participants This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human subjects.
Statement of Consent	Your signature indicates that you are at least 18 years of age; you have read this consent form or have had it read to you; your questions have been answered to your satisfaction and you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form. If you agree to participate, please sign your name below.
Signature and Date	**NAME OF PARTICIPANT** **[Please Print]** |
	SIGNATURE OF PARTICIPANT |
	DATE |

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CONSENT TO PARTICIPATE

Project Title	Peripheral and central contributions to auditory temporal processing deficits and speech understanding in older cochlear implantees: Non-Cochlear Implant Participants
Purpose of the Study	This research is being conducted by **Matthew Goupell** at the University of Maryland, College Park. We are inviting you to participate in this research project because you have typical hearing. The purpose of this research is to learn how people with cochlear implants hear sounds and understand speech. People with cochlear implants tend to struggle to understand speech, particularly in difficult environments like background noise. We are seeking information on how the brain processes sounds from the cochlear implant(s) to improve how the devices work. Data from listeners with typical hearing is needed for comparison.
Procedures	The procedures involve one or more of the following: 1) A standard test of hearing for both of your ears. (Required) 2) A basic vision test. 3) Listening to sounds over headphones or over loudspeakers in a quiet room. You will then respond to differences in sounds or report what you heard, usually with a computer keyboard, mouse, or with a spoken response. 4) Listening to and/or reading sentences, words, or numbers. 5) Watching videos of people speaking, both with and without sound 6) Answering questions and following simple instructions that are designed to measure memory and attention. 7) Measurement of small electrical responses from the surface of your head and skin. You will sit in a reclining chair. Standard silver-silver chloride electrodes will be placed on your head with electrode paste. You will watch movies on DVD. You will hear speech or other sounds through headphones, earphones or loudspeakers. The electrodes will measure brain waves specific to hearing. 8) Listening to sounds and speech while seated at an eye tracker. The eye tracker is a remote camera that measures where you are looking and your pupil size across time. This measurement is made while you rest your head on a chin rest and/or forehead bar. Your speech when repeating words and sentences may be audio-recorded for scoring. You may choose to not have your voice recorded and to not take part in that part of this study. The above procedures typically take 1 to 6 hours, usually in 1- to 2-

	hour blocks of time, over about one to two months, depending on your schedule and availability. We may ask if you would be willing to continue for an additional time, depending on the experiment. There will be no pressure on you to continue if you want to stop at any time. You do not need to take part in all tasks and may choose to only complete some parts of the study. Not all participants will be invited to complete all procedures. All testing will take place in the Hearing and Speech Sciences Department at the University of Maryland at College Park in quiet rooms like a sound booth or sound-treated chamber.
Potential Risks and Discomforts	There may be some risks from participating in this research study. The tests can be repetitive and boring for some people. You will be allowed frequent breaks to reduce boredom, fatigue, or discomfort from sitting or standing during our tests. You will be asked to listen to sounds presented either over the headphones or from loudspeakers in quiet rooms. The sounds are always presented at comfortable loudness levels, and will never intentionally be uncomfortably loud or unsafe. On rare occasions, some people experience minor, temporary skin irritation from the electrode paste. This can be reduced by washing with water. If eye tracking is completed, there is additional risk of discomfort from having one's head still in a chin rest and/or forehead bar during testing. Frequent breaks will be provided. Eye trackers employ a low level of infrared light to track pupil size and position. The amount of infrared light exposure is less than 7.5% of the maximum allowable exposure and comparable to the amount of exposure experienced on a bright, sunny day. As in all research studies, there is the potential risk for the loss/breach of confidentiality. These risks will be reduced using the measures described below in the Confidentiality section.
Potential Benefits	This research is not designed to help you personally, but the results may help the investigator learn more about how the auditory system functions, and might in the future help us to improve the design of hearing aids and cochlear implants.
Confidentiality	Any potential loss of confidentiality will be minimized by assigning a participant code to your information and storing your data in a locked office and on password protected computers. The identification key between your real name and your code will be kept in a different location to the data, and can only be accessed by the researcher. This research will probably be published in a scientific

	journal, but will not contain any material that will identify you as a participant. Records are kept at least 7 years past the time of publication of the results in peer-reviewed journals as per NIH policy, and likely longer. When the data are no longer needed, any paper with identifiable information will be shredded through a university-approved shredding service and all digital files will be deleted. If we write a report or article about this research project, your identity will be protected to the maximum extent possible. Your information may be shared with representatives of the University of Maryland, College Park or governmental authorities if you or someone else is in danger or if we are required to do so by law.
Compensation	For your part in this study, you will be paid as a Research Participant at a rate of $15.00 per hour. You will be responsible for any taxes assessed on the compensation. If you will earn $100 or more as a research participant in this study, you must provide your name, address and SSN to receive compensation. If you do not earn over $100 only your name and address will be collected to receive compensation.
Right to Withdraw and Questions	Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify. Circumstances that the researcher may terminate subject participation for include: 1) Having a hearing loss or hearing asymmetry that does not meet the requirements of the study 2) Inability to keep scheduled appointments If you are an employee or student, your employment status or academic standing at UMD will not be affected by your participation or non-participation in this study. If you decide to stop taking part in the study, if you have questions, concerns, or complaints, or if you need to report an injury related to the research, please contact the investigator:

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Participant Rights	If you have questions about your rights as a research participant or wish to report a research-related injury, please contact: University of Maryland College Park Institutional Review Board Office 1204 Marie Mount Hall College Park, Maryland, 20742 E-mail: irb@umd.edu Telephone: 301-405-0678 For more information regarding participant rights, please visit: https://research.umd.edu/research-resources/research-compliance/institutional-review-board-irb/research-participants This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human subjects.	
Statement of Consent	Your signature indicates that you are at least 18 years of age; you have read this consent form or have had it read to you; your questions have been answered to your satisfaction and you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form. If you agree to participate, please sign your name below.	
Signature and Date	**NAME OF PARTICIPANT** **[Please Print]**	
Signature and Date	**SIGNATURE OF PARTICIPANT**	
	DATE	