Informed Consent Document for Research
STUDY SITE INFORMATION

Study Title: Binaural cue sensitivity in children and adults with combined electric and acoustic stimulation

Version Date: 10/21/2022

IRB APPROVED
Apr 15, 2025

Part 1 of 2: MASTER CONSENT

TITLE: Binaural cue sensitivity in children and adults with combined electric and acoustic stimulation

PROTOCOL NO.: NIDCD R01 DC020194
WCG IRB Protocol #20251330

SPONSOR: NIDCD

INVESTIGATOR: Rene Gifford, PhD
11500 Portland Ave
Oklahoma City, Oklahoma 73120
United States

STUDY-RELATED PHONE NUMBER(S): 405-548-4300

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

Name of participant: _____ Age: _____

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

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Key information about this study:

This study is looking at the benefit of electric and acoustic hearing in the same ear for cochlear implant (CI) patients. Even though this type of hearing is becoming more common, there is limited research on how it can be beneficial to CI users, especially in children. The benefits of this study are a greater understanding of your speech understanding, binaural processing, and spatial hearing. The results will help audiologists and researcher better understand how cochlear implants work, specifically when using electric and acoustic hearing in the same ear. Your alternative is to not take part in the research. Approximately 100 participants will be enrolled at Hearts for Hearing. The study will require you to complete 1 visit, ranging in time from 1-10 hours over 1-2 days. The research poses no known risk to your health and well -being. Potential risks are breach of confidentiality, and discomfort and boredom while performing the tasks. Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because we are gathering data to describe how adults and children with normal hearing perform on various tasks of speech understanding, binaural processing, and spatial hearing.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Side effects and risks that you can expect if you take part in this study:

Potential risks are minimal. The research poses no known risk to the health and well -being of participants.

One potential risk is that your confidentiality could be breached. We will safeguard this by using participant labels, rather than names or initials, and not including any information that could be identifiable such as date of birth.

Another potential risk is the boredom that you may experience during the study visits; however, frequent breaks will be provided.

Risks that are not known:

There are no known unforeseeable risks associated with study participation. It is possible there may be other risks that we are unaware of.

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Good effects that might result from this study:
The benefits to science and humankind that might result from this study include implications for auditory scientists, clinical audiologists, and manufacturers of cochlear implants. Regardless of the outcome, the cochlear implant community will have a greater understanding of speech understanding, binaural processing, and spatial hearing for adults and children with cochlear implants and adults and children with normal hearing.

Procedures to be followed:
The study will require you to complete 1 visit, ranging in time from 1-10 hours over 1-2 days.

Study visits will include hearing tests in a sound treated booth, as well as assessments of speech understanding, binaural processing, and spatial hearing. We will also ask that you fill out surveys about how you feel and believe you hear in different listening environments. You will be given a screening of cognitive function. Participation in this study will include 1) listening to words and sentences in quiet and in noise and repeating the sentences, 2) listening to different noise-like sounds and making judgments about those sounds, 3) and/or sitting quietly while we measure electrical responses to the auditory stimuli using electrodes placed on the scalp, forehead, and earlobe and 4) filling out a questionnaire asking questions about how you feel you hear. Speech and language assessments will involve you answering questions about images shown in a picture book designed to require that you produce all speech sounds and repeating words or solving auditory and visual patterns. We may be audio and video recording your assessments so that we may use the recordings to analyze your speech and language patterns after the study visits.

Reasons why the study doctor may take you out of this study:
Should you be unable to complete the assessments required for study participation, the principal investigator may withdraw you from the study. Should this occur, you would still be compensated for the time spent participating and you would still be reimbursed for your mileage up to that point.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your medical care in any way. The data collected up to the point of study withdrawal will be used for scientific analysis.

Clinical Trials Registry.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done

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on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
If requested, you will receive a written report of your performance on auditory, speech and language assessments following the study visit. This report will be emailed to you.

Part 2 of 2: STUDY SITE INFORMATION

Site Name:	Hearts for Hearing
Site Principal Investigator:	René H Gifford, PhD
Site Principal Investigator Contact:	405-548-4300

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Payments for your time spent taking part in this study or expenses:
You will be compensated at a rate of $15 per hour for your time spent participating that will be paid in the form of a gift card at the end of each study visit. For visits that are 4 or more hours, you will also be reimbursed for your mileage at the IRS approved rate for travel to and from Hearts for Hearing for each study visit (up to 400 miles roundtrip). Your mileage reimbursement will be paid to you in the form of a check mailed to your home. It is expected that the check will arrive to you 6 to 8 weeks following each study visit. If you choose 2 full days, you will be reimbursed for 3 meals on each day of testing up to $80/day and hotel accommodations will be provided. If you live outside of driving distance to Hearts for Hearing and you are participating for more than 4 hours, we can provide you with airfare and hotel accommodations for the study visits. *All travel arrangements must be approved by the study team prior to booking.*

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Hearts for Hearing and the Investigator with NIH input that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at **Hearts for Hearing** to treat the injury. There are no plans for Hearts for Hearing or NIH to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Hearts for Hearing or NIH to give you money for the injury.

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Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Gifford at 405-548-4300.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, complaints and questions, or to offer input, please feel free to WCG IRB at 855-818-2289, or clientcare@wcglinical.com.

Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Confidentiality will be maintained through the use of subject codes that preclude subject identification. Other information, such as date of birth or date of surgery, will be presented in a manner that does not identify the subject; such as "age at test" or "experience with the device". Medical release obtained regarding any participant will be restricted to audiological information relevant to the current study.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Hearts for Hearing and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Hearts for Hearing, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Hearts for Hearing. This may include

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the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, WCG IRB, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of participant

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____