Coversheet for Informed Consent

Title: Pediatric Image-Guided Cochlear Implant Programming

NCT Number: NCT03886168

Date: 11/25/2025

Date of Approval from IRB: 10/29/2019

PI: Stephen Camarata

Study Title: Image-Guided Cochlear Implant Programming: Pediatric Speech, Language, and Literacy
Version Date: 10/29/2019

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: Image-Guided Cochlear Implant Programming: Pediatric Speech, Language, and Literacy
Version Date: 10/29/2019
PI: René Gifford, PhD and Stephen Camarata, PhD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

What is the purpose of this study?
You and your child are being asked to take part in this research study because we are gathering data to describe how children with normal hearing perform on various tasks of auditory processing, speech understanding, speech production, language, and reading.

Side effects and risks that you can expect if you take part in this study:
The most obvious side effect of participation is the boredom that your child will experience during the study visits; however, frequent breaks will be provided.

There is a potential risk is that your child's 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.

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.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study:

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Results from this study will have implications for auditory scientists, clinical audiologists, speech-language pathologists, and manufacturers of cochlear implants. These data will be used to benchmark the outcomes of children with cochlear implants. Thus the cochlear implant community will have an enhanced understanding of how children with implants perceive speech, resolve pitches in speech sounds and are able to improve on measures of auditory processing, speech production, language, and reading as compared to children with normal hearing.

Procedures to be followed:
The study will require your child to complete 1 to 2 study visits for an estimated total of 7 to 8 hours of testing. Study visits will include various hearing tests in a sound treated booth, as well as assessments of

speech, language, and reading. We will also ask that you and your child fill out up to 3 surveys about how you and your child believe s/he feels at home and at school and how s/he hears in different listening environments.

Hearing assessments will involve 1) listening to words and sentences in quiet and in noise and repeating the sentences, and 2) listening to different tone- and noise-like sounds and making judgments about those sounds and/or sitting quietly while we measure electrical responses to the auditory stimuli using electrodes placed on the scalp, forehead, and earlobe and

Speech production, language assessments, and reading assessments will involve your child 1) answering questions about images shown in a picture book designed to require that s/he produce all speech sounds, and 2) repeating words or solving auditory and visual patterns.

We will be audio and video recording your child's assessments of speech, language, and hearing so that we may use the recordings to analyze his/her speech and language patterns after the study visits.

Payments for your time spent taking part in this study or expenses:
Your child will be compensated at a rate of $10 per hour ($80) for his/her time spent participating that will be paid in the form of a gift card at the end study completion. You will also be reimbursed for your mileage at the IRS approved rate for travel to and from Vanderbilt for each study visit (up to 300 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.

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 Vanderbilt 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 Vanderbilt** to treat the injury.

There are no plans for Vanderbilt or the 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 Vanderbilt or the NIH to give you money for the injury.

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 or Dr. Camarata** at **615-936-5000.**

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Should your child be unable to complete the assessments required for study participation, the principal investigators may withdraw your child from the study. Should this occur, your child 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?

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If you and/or your child decide to stop being part of the study, you should tell Dr. Gifford or Dr. Camarata. Deciding to not be part of the study will not change your or your child's 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 www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

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, will be presented in a manner that does not identify the subject; such as "age at test". Medical release obtained regarding any participant will be restricted to audiological information relevant to the current study.

This study is supported 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.

Privacy:

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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 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:

You will receive a written report of your child's performance on auditory, speech, language, and literacy assessments following each study visit. This report will be emailed to you approximately 2 weeks following the study visit.

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 Vanderbilt University Medical Center 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 Vanderbilt, 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 Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, 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?

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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 patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____