Official Title:	A computational approach to optimal deactivation of cochlear implant electrodes
NCT Number:	NCT05219474
Study Number:	s21-01661
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NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	A computational approach to optimal deactivation of cochlear implant electrodes S21-01661
Principal Investigator:	Elad Sagi, PhD Department of Otolaryngology NYU Grossman School of Medicine 550 First Ave., NBV-5E5, New York, NY, 10016 212-263-7765
Emergency Contact:	911

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The goal of the present study is to use computer models to guide the search for which combination of cochlear implant active electrodes can yield the best speech understanding for a specific patient.

3. How long will I be in the study? How many other people will be in the study?

The study will last two years. If you use a cochlear implant, you will be expected to participate in 7 visits over a six-month duration. Each visit will last 3 hours. If you do not use a cochlear implant and have normal hearing, you will be expected to participate in 1 visit lasting 3 hours.

For this study, we will enroll 24 cochlear implant subjects and 30 normal hearing subjects. All subjects will be tested at NYULMC.

4. What will I be asked to do in the study?

If you use a cochlear implant:

You will be given several tests that require you to listen to sounds presented to your cochlear implant and answer questions about those sounds. These tests will be used to measure your performance with your current clinically assigned device settings and with three possible experimental settings that involve different recommendations of which electrodes in your CI should be deactivated. Two of those recommendations will be based on your sensory abilities with your CI. One of those recommendations will be based on a computer model of your sensory and speech understanding abilities.

Your first three visits will involve baseline testing with your clinical settings. Each visit will last 3 hours. We will measure your sensory abilities, speech understanding abilities, and sound quality you experience with your clinical device settings. These measures will be used to construct a computer model of your performance. This computer model will be used to provide a specific recommendation of which electrodes to deactivate in your CI settings.

About 6 weeks after your initial visit, you will return for your 4th visit lasting 3 hours. We will program one of the three experimental settings into your CI, and evaluate your speech understanding and sound quality with those experimental settings. Your clinical settings will still be available to you in your CI if you feel the need to use them at any time. We will ask you to use the experimental settings for at least 1 hour daily.

About 6 weeks after your previous visit, you will return for your 5th visit lasting 3 hours. We will evaluate your speech understanding and sound quality with the experimental settings assigned in your previous visit. We will then program one of the other two remaining experimental settings into your CI, and evaluate your speech understanding and sound quality with those experimental settings.

About 6 weeks after your previous visit, you will return for your 6th visit lasting 3 hours. We will evaluate your speech understanding and sound quality with the experimental settings assigned in your previous visit. We will then program the last remaining experimental settings into your CI, and evaluate your speech understanding and sound quality with those experimental settings.

About 6 weeks after your previous visit, you will return for your final visit lasting 3 hours. We will evaluate your speech understanding and sound quality with the experimental settings assigned in your previous visit.

If you do not use a cochlear implant and have normal hearing:
You will be asked to participate in one testing session lasting 3 hours. You will be given several tests that require you to listen to sounds and answer questions about those sounds. The sounds will be distorted in ways that approximate how a cochlear implant sounds. These tests will be used to measure your sensory acuity and speech understanding with acoustic models of cochlear implants

Any identifiable data collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

There is a risk of hearing loud sounds that may be unpleasant (but are not harmful). To avoid this, we will check the stimuli to be used in every testing session before we use them. There is also a risk of becoming tired and/or bored because of the repetitive nature of some tasks. To minimize these issues, you can take breaks as often as required.

If you use cochlear implant, experimental settings may cause speech understanding to become poorer than with clinical settings. To minimize this risk, your clinical settings will be programmed into your device together with experimental settings, and you can switch to the clinical settings as often as needed. However, we will ask you to use the experimental settings as much as possible, and at least daily for 1 hour.

There is a risk of breach of confidentiality. To minimize this risk, hard copies of your information will be stored in locked cabinets in our laboratory and electronic copies will be stored in password protected files protected by the NYULH firewall.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

If you have a cochlear implant, it is possible that some study subjects may experience an improvement in their speech understanding and sound quality while using experimental CI settings during the study. If you receive such benefit, your audiologist can program these settings into your device after you finish the study. Also, you may not get any benefit from being in this research study.

If you do not have a cochlear implant, you will not benefit from taking part.

Others with cochlear implants may benefit in the future from what we learn in this study.

8. What other choices do I have if I do not participate?

You are free to choose not to participate in this study. Your choice will **not** affect the ongoing care you receive.

9. Will I be paid for being in this study?

You will be paid $15.00 per hour for your participation plus public transportation costs or parking costs. Payment will be issued in the form of an NYU ClinCard or prepaid giftcard at the end of each session. This will not be affected in any way should you withdraw from the study prior to completion. Because the visits are expected to last about 3 hours each, the maximum amount of payment per visit is $45. A maximum of $45 will be paid for transportation/parking costs.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment, you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

You must let us know immediately if/when the total research payments presently equal or are likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please tell the PI on page 1. However, you are required to report to the IRS all payments made to you by NYU Langone for your participation in any research for this calendar year, even payments under $600.00.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

10. Will I have to pay for anything?

You and/or your health insurance will not be billed for the costs of tests and procedures required solely for this study.

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

In the unlikely event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. You should understand also that it is your responsibility to determine the extent of your health care coverage.

There are no plans for the NYU Grossman School of Medicine or NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the principal investigator or study sponsor without your consent because:
The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
You have not followed study instructions.
The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institute of Health
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).

- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. Electronic Medical Record and Release of Study-Related Information

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you have a cochlear implant:
If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by NYU Langone Health. This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?

The 21st Century Cures Act allows patients increased access to their EMR. If you agree to participate in this study, this means that any research-related information placed in your EMR will be available to you immediately.

As a research participant, this means that you have immediate access to any research-related information that is placed in your EMR before the researchers have had an opportunity to review the information.

In this study, some research-related information will never be made available to you in your EMR. This information will not be accessible in your EMR because the information is specific to this research and is not part of your medical history and clinical care.

- ***Results that will not be placed in the medical record:***
  - Cochlear implant device settings used for experimental conditions
  - speech testing and sound quality measures obtained during research sessions

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, scientists, and people from the community.

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://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 website at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent of Non-English Speaking Subjects Using the "Short Form" in Subject's Spoken Language

Statement of Witness
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness
I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date