Official Title:	Stimulating the cochlear apex without longer electrodes
NCT Number:	NCT06901674
Study Number:	s20-01964
Document Type:	Informed Consent Form
Date of the Document:	• July 29, 2024

NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form

Title of Study:	Stimulating the cochlear apex without longer electrodes i20-01964
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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. There are no penalties for refusing to participate in the 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 purpose of this study is to see if a novel (new) surgical method with a standard cochlear implant can improve hearing at lower frequencies. While a standard cochlear implant electrode array, which sends electrical signals between the cochlear implant device and the cochlea, can provide a full range of frequency information, it provides the information to a region of the cochlea which is used to only receiving higher frequency information. This may result in sounds being perceived as higher in pitch than would be perceived with a typically-hearing ear.

In this study, a typical cochlear implant will be inserted with the addition of an extra electrode placed in the region of the cochlea, known as the apex, that is used to hearing lower-frequency sounds. By using this additional electrode, you may be able to perceive lower-pitched sounds which could improve speech understanding and sound quality.

You are asked to take part in this study because you fit our study criteria, and as part of your clinical care, you have chosen to be implanted with a Nucleus Cochlear implant system produced by Cochlear Limited, or because you have already been implanted with a Nucleus Cochlear Implant system produced by Cochlear Limited with or without this novel surgical approach.

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

You may be asked to return for up to 10 testing sessions over the course of two years. Approximately 40 participants will be asked to participate in this study. Some participants will be receiving a cochlear implant with a novel surgical approach. Others may have already received a cochlear implant, with or without the novel surgical approach.

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

If you are receiving a cochlear implant using the novel surgical approach, then in addition to the standard insertion of an electrode array during your surgery, an additional single electrode will be placed deeper into the cochlea. The procedures involved in evaluating your cochlear implant and the follow up that is provided after the surgery are considered to be standard of care (which means, you would undergo these procedures as a candidate for cochlear implant surgery regardless of your participation in this study). Your doctor will discuss your standard care follow-up schedule and procedures with you.

The only difference is that the additional electrode will be placed in the top of your cochlea where lower frequency information is heard instead of underneath a large muscle on the side of your head called the temporalis muscle. This adds approximately 2-5 minutes to the surgery and does not affect the normal functioning of the cochlear implant. The postoperative recovery is the same as with any cochlear implant surgery.

As part of this study, you will have to complete more speech understanding tests, and other tests where you will also be asked to listen to sounds delivered through your implant. After listening to the sounds, you will be asked to register your judgments orally, on a response box or on a computer screen.

The testing sessions will take place at a time determined by you in consultation with the New York University Medical Center research staff. In general, each session will last about 4-6 hours. These testing sessions are in addition to standard clinical appointments that are necessary for new cochlear implant recipients.

If you have already received a cochlear implant with or without the novel surgical approach outside of this study, then you will only be asked to listen to sounds delivered through your implant. After listening to the sounds, you will be asked to register your judgments orally, on a response box or on a computer screen.

The testing sessions will take place at a time determined by you in consultation with the New York University Medical Center research staff. In general, each session will last about 4-6 hours.

If you are unable to travel to the audio research lab for these testing sessions, there is the option to participate in the research in your own home or another quiet location that is more convenient. All equipment used in these experiments is portable and can be safely used outside our traditional testing environments. A study team member will come to the agreed upon location to conduct testing. To maintain a safe working environment, the team member will wear a mask at all times during the testing session and sanitize all equipment prior to conducting testing, as well as at the conclusion of the testing session. We ask that you also wear a mask for the duration of the testing session.

Please speak with one of the research team members if you would like to discuss this possibility.

Any identifiable private information 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?

If you are receiving a cochlear implant as part of this study, then there are no foreseen surgical risks beyond those associated with a standard cochlear implant surgery. Your doctor will discuss these risks with you as part of your standard medical care.

We do not anticipate any added risks to you as a result of prolonging your procedure by an extra 2-5 minutes in order to place the electrode into the top of your cochlea.

For the testing sessions with your cochlear implant, the risks posed as a result of your participation are minimal. You may receive loud or otherwise uncomfortable sounds, but you may terminate them at any time by removing the external transmitter. The techniques for removing the external transmitter will be demonstrated before testing occurs. The stimuli in these experimental tests will not damage your implant, or endanger your future use of the implant.

Because the sessions last between 4-6 hours, you may feel tired or frustrated.

Unforeseeable Risks

There may be side effects or other risks that are not known at this time. The risk of loss of confidentiality always exists, but there are procedures in place to minimize these risks.

Other Risks

Your condition may not get better or may get worse during this study.

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 will be receiving a cochlear implant with the novel approach, you may hear lower pitched sounds better as a result of participating. This may result in better sound quality and speech in noise performance with your cochlear implant. However, we don’t know if you will benefit from this experimental surgical modification. It is possible you won’t benefit. We hope the information obtained in this study will help future patients receiving cochlear implants.

If you already have a cochlear implant with or without the novel surgical approach, there will be no additional benefit in participating in this study as your involvement will be limited to completing listening tasks.

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

The alternative is not to participate in this study. You do not need to participate in this study to receive a cochlear implant.

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

You will be compensated $15 per hour for each completed hour of the research testing sessions only. Compensation will not be provided for any surgical, medical or standard clinical appointments that are necessary for new cochlear implant recipients.

If you complete all the study visits, you could receive up to $1200 for being in this study.

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

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is 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 advise David Landsberger by email at David.Landsberger@nyulangone.org.

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, and you may be taxed on these research payments above $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 a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

Transportation reimbursement will be provided for public transportation costs or parking costs within the greater New York City area. A maximum of eight hours of parking per sessions will be reimbursed. This reimbursement pertains only to the testing sessions.

Transportation reimbursement will not be provided for any surgical, medical or standard clinical appointments that are necessary for new cochlear implant recipients.

10. Will I have to pay for anything?

If you have already been implanted with a cochlear implant with or without the novel approach, they you will not need to pay for anything in this study.

If you are receiving a new cochlear implant as part of 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, the study team will assist in obtaining funding to cover related expenses.

You or your insurance company may be billed for:

- Any standard medical care given during this research study.
- The cochlear implant system and all associated surgical procedure
- Medical, surgical, or audiological treatment outside of the study intervals that you might require after receiving the cochlear implant.

It is not anticipated that there will be any additional costs associated with your participation in this study.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

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.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU School of Medicine or Medical Center 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 PI 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.

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
- Government 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.
- Other study sites involved in the research

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. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

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Subject Initials

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, non-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.

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