Informed Consent

Place-based mapping in electric-acoustic stimulation listeners

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University of North Carolina at Chapel Hill Consent to Participate in a Research Study Adult Participants
Consent Form Version Date: August 31st, 2023 **IRB Study #** 20-3022

Title of Study: Place-based mapping in electric-acoustic stimulation listeners
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CONCISE SUMMARY: COCHLEAR IMPLANT SUBJECTS

The purpose of this study is to evaluate a new mapping (programming) method as compared to the current default mapping method for cochlear implant patients.

We will use your postoperative CT scan to determine the location of your cochlear implant in your cochlea (hearing organ). We will use that information as part of a new mapping method. We call the new mapping method "place-based" mapping.

At initial activation of your external device, you will be randomized to receive either the default map or the place-based map. We will test your performance at the following intervals: device activation, 1-month, 3-month, 6-month, and 12-months after activation. These intervals are the same as recommended by your clinician.

Testing will not exceed 3 hours, depending on the interval. The only risk is fatigue during testing. You may experience improved performance with your device as part of participating in the study.

You will be compensated $15.00 per hour for your effort on research-related procedures.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to determine whether specific mapping (programming) procedures of cochlear implant devices improve subject performance (e.g., speech understanding). The mapping procedures use the FDA-approved clinical programming software for your cochlear implant.

You are being asked to be in the study because you received a MED-EL cochlear implant device, and are between 18 and 80 years of age.

Are there any reasons you should not be in this study?

You should not be in this study if you do not want to participate, or do not plan to follow-up with the cochlear implant team at the Carolina Crossing location.

How many people will take part in this study?

Approximately 80 people at will take part in this study.

How long will your part in this study last?

Your part in the study will be approximately 1 year. We will test you at the follow-up intervals recommended by your clinician for all cochlear implant patients. These include: device activation, 1 month, 3 month, 6 month, and 12 months post-activation. Testing will not exceed 3 hours at each interval.

What will happen if you take part in the study?

Your postoperative CT scan results will be used to determine the location of your cochlear implant in your cochlea (hearing organ). We will use that information as part of a new mapping method. We call the new mapping method "place-based" mapping.

You will be randomized to receive the manufacturer default map or the place-based map at the activation of your device. Your performance (e.g., speech understanding) will be tested after your device is activated.

You will be tested at the following intervals: 1 month, 3 month, 6 month, and 12 month post-activation. At each interval, you will complete questionnaire(s) and be tested by a member of the research team. Testing will include measures of your speech understanding, spatial hearing abilities (e.g., localization), and your perception of the sounds of the cochlear implant. The tester will be blinded to the specific map (default or place-based) that you have.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You may experience an improvement in your performance with your cochlear implant as part of participating in the study.

What are the possible risks or discomforts involved from being in this study?

You may experience fatigue during testing. If you feel fatigued during testing, please tell the researcher and he/she will provide you with a break.

The risk of breach of confidentiality is low, as you will be tested at the same location as other cochlear implant recipients who are not participating in research and your identifiable information will be kept separate from your study data.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

Will I receive any other clinical results?

Other clinically relevant results of this research will be communicated with you, such as your speech understanding scores measured at each interval.

How will information about you be protected?

Your results will be coded as part of the research study. The link between your name and your subject identification number will be kept on a password-protected flash drive, which will be kept in a locked cabinet. Only members of the research team will be able to access this information.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Your audiogram (hearing test) and speech perception results will be entered into your medical record since this information is also used by your clinical team (audiologist, physician) in the assessment of your cochlear implant.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What is a Certificate of Confidentiality?

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will be receiving $15.00 per hour on research-related activities (i.e., speech understanding, localization, subjective questionnaires, pitch perception) for taking part in this study. Any payment provided for participation in this study may be subject to applicable tax withholding obligations. Time spent as part of routine clinical care (i.e., mapping (programming) of your device) will not be compensated.

The costs of acoustic programming, the earmold impression, earmold, and tubing will be covered by the study.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by the National Institutes of Health (NIH) (the sponsor). This means that the research team is being paid by the sponsor for doing the study. In addition, Dr. Kevin Brown, a co-investigator on the study, and Andrea Bucker, a research team member, receive money from MED-EL Corporation for work that is not part of this study. Andrea Bucker also receives money from Advanced Bionics Corporation and Cochlear Americas for work that is not part of this study. These activities may include consulting, service on advisory boards, giving speeches, or writing reports. Advanced Bionics, Cochlear Americas, and MED-EL Corporation are companies with an interest in the outcome of this study.

If you would like more information, please ask the researchers listed in the first page of this form.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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 website at any time.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Unencrypted Communication Consent

The following information is regarding un-encrypted communication (e,g., texting or email) by study staff and should be read as an addition to the consent information you have already been provided. All information previously provided is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study team.

The study team would like to message you by email, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this addendum to the consent. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following email address to send communication:

_____

_____ No, I do not consent to receive un-protected communication from the study team.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

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Signature of Research Participant Date

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Printed Name of Research Participant

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Signature of Research Team Member Obtaining Consent Date

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Printed Name of Research Team Member Obtaining Consent

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Signature of Witness if applicable; e.g. literacy issues,
visually impaired, physically unable to sign, witness/interpreter for
non-English speaking participants using the short form)

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Printed Name of Witness

_____

Date