University of Pittsburgh

School of Medicine
Department of *Otolaryngology*

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Single Sided Deafness (SSD)-Cochlear Implant **Principal Investigator:**

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Source of Support: The Department of Otolaryngology

KEY INFORMATION:
You are being asked to participate in a research study. This is not a form of treatment. It is not supposed to detect a disease or find anything wrong. Research Studies like this one include only people who choose to volunteer to participate. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

Permanent single-sided deafness (SSD) is a common problem that leads to changes in connections in the brain. The purpose of this research is to investigate how the length of time a person has SSD can influence how their brain adjusts to a cochlear implant (CI) and how this impacts how well a person can hear both sound and human speech.

This research will involve people who have SSD as well as people who are not currently experiencing any hearing problems.

Using functional near infra-red spectroscopy (fNIRS) testing, we are now capable of identifying changes in the brain related to SSD. fNIRS can measure brain activity of a specific area of your brain by analyzing the amount of oxygen being sent to it. We will also be using traditional electroencephalography (EEG) testing, (recording of electrical brain wave activity), hearing related testing and several questionnaires in this research.

Research Participants with SSD:

- If you decide to participate in this research, you will be asked to complete a total of 7 research visits. There will be 2 different types of research visits. One type will be called the **fNIRS visit** and one will be called the **EEG visit**. These visits will take place over the course of the next 18 months. Today, we will collect your contact information so that we can keep in contact with you and schedule your future visits. These future visits will be outlined in detail below but will involve fNIRS testing (approximately 90 minutes), completion of surveys/questionnaires related to SSD (approximately 15 minutes), Sound Localization testing (approximately 30 minutes) and Electroencephalography (EEG) testing/Pupillometry/Listening tests (no more than 3.5 hours). The information collected may be stored forever. Research may be performed by researchers within UPMC and the University of Pittsburgh. Personal, identifiable information will not be shared outside of this project.

- As part of this research, we will need to access your medical records. Please know that any information that we collect from your medical record will be the smallest amount needed to help us with our research. Personal, identifiable information will not be shared outside of this project.

- You will not receive any direct benefit if you participate, but the researchers may discover important information about SSD that could help patients in the future.

Research Participants who do <u>NOT</u> have SSD (CONTROLS):

- If you decide to participate in this research, you will be asked to complete a total of 2 research visits. There will be 2 different types of research visits. One type will be called the **fNIRS visit** and one will be called the **EEG visit**. These visits will take place over the course of the 2-3 months and in most cases can be scheduled within the next few weeks. Today, we will collect your contact information so that we can keep in contact with you and schedule your future visits. These future visits will be outlined in detail below but will involve fNIRS testing (approximately 90 minutes), completion of surveys/questionnaires related to SSD (approximately 15 minutes), Sound Localization testing (approximately 30 minutes) and Electroencephalography (EEG) testing/Pupillometry/Listening tests (no more than 3.5 hours). The information collected may be stored forever. Research may be performed by researchers within UPMC and the University of Pittsburgh. Personal, identifiable information will not be shared outside of this project.

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- You will not receive any direct benefit if you participate, but the researchers may

discover important information about SSD that could help these patients in the future.

Why is this research being done?

- This research study is designed to look at whether the length of time a person has SSD determines how well they are able to hear after receiving a cochlear implant (CI). Information to be collected will include brain recordings using fNIRS and EEG technology as well as information collected from several questionnaires and information collected during specific types of hearing testing. Information will be collected from patients who have SSD as well as from patients who do not have SSD (controls). As SSD participants are enrolled, they will be divided into groups based on the length of time of their SSD. These groups include:
    - early SSD less than 12 months of duration
    - mid SSD from 12months to 5 years duration
    - late SSD over 5years of duration

  Once a specific group has been filled, recruitment for that group will stop.

Who is being asked to take part in this research study?

You are being asked to participate in this research because you are an adult, 18-65 years of age who is being seen for the evaluation of SSD. **OR** you are an adult, 18-65 years of age being seen by a member of the Department of Otolaryngology clinical team for a reason other than SSD (Control). We are looking to enroll about 150 people overall (with SSD and Controls) to participate in this research.

What procedures are being performed for research purposes?

If you decide to participate in this research, we will ask you to complete the following tasks.

Enrollment Visit – SSD subjects AND Controls (less than 30 minutes)

At this visit, we will review the consent form, answer any questions you may have about the research study and, if you agree to participate, your informed consent will be obtained. Additionally, at this visit, we will collect your contact information (phone number/email) so that we can contact you to set up the future visits.

We expect that all research-related tasks for Controls to be completed within 2-3 months of enrollment. We anticipate the number of visits for Controls to be 2.

We expect that all research related tasks for SSD subjects to be completed within 18 months of enrollment. We anticipate the number of visits for SSD subjects to be 7.

<u>VISIT 1 – EEG Testing Visit – (SSD subjects AND Controls)</u>

The length of EEG testing visit will be approximately 3.5 hours You will be asked to report to Forbes Tower for the EEG testing visit.

The visit will include the following:

You will be seated in a sound-treated booth in a reclining chair. You will have several "surface electrodes" placed on the surface of your skin. Areas that will have electrodes will include the forehead, scalp, earlobe and ear canal. These surface electrodes will be coated with a gel/paste that helps them to record electrical activity from your brain. These are recording electrodes only. No outside electrical stimulation will be delivered to you/your skin.

You will also have small "tiptrodes" placed in your ears. These tiptrodes have a small hole in the middle of them that connects to the testing equipment. Sound will be delivered through the tiptrodes during portions of the research visit. Sounds may be brief "clicks" or tones or other sounds. Sounds may be delivered in one or both ears at a time. The research staff will work with you to find a comfortable level of volume for these sounds.

Once the surface electrodes and the tiptrodes are in place, you will receive detailed instructions on exactly what you will need to do for the remainder of the session. These tests will involve listening to speech or isolated words, or to short sounds in the presence of noise or other competing sounds. We will then ask you to respond to these sounds either by speaking the sentence out loud or by pressing a button on a computer.

Pupil Dilation Measurement – (during EEG testing)

During your testing, there will be times when the research staff will measure the size of the pupils in your eyes. This will occur while you are looking at a screen performing the tasks that have been explained to you by using a device known as a pupillometer. The pupillometer is a camera that is aimed at your eye to capture changes in your pupil. These measures will give us an idea of how difficult you find the task to be. These tests will identify the ways in which you perceive sound in noise environments.

Sound Detection – (during EEG testing)

During your EEG testing visit, you will be presented with a tablet computer and some headphones. (the tiptrodes will be removed during this part of the visit) While using the tablet, you will be asked to identify different sounds or words that are presented to you through the headphones. You will be given specific instructions for each of these tasks.

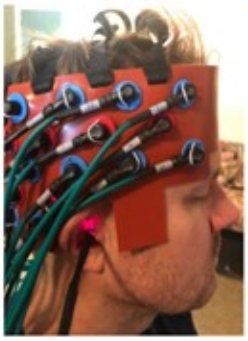
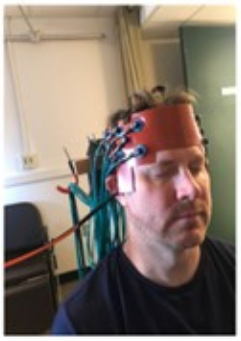
VISIT 2 – fNIRS Testing Visit – (SSD subjects AND Controls)

Length of fNIRS visit will be approximately 2 TO 2.5 hours

You will be asked to report to Forbes Tower for the fNIRS testing visit.
This visit will include the following:

fNIRS testing - (90 minutes) The room where the testing is being performed has a computer with 2 speakers and the fNIRS machine. You will be seated in a chair with a footrest to make you feel more comfortable. A cap will be placed on your head and held in place using Velcro straps. There are holes in the cap that will hold probes in place. These probes are what will

measure your brain activity. The cap will be adjusted and positioned so that the probes are located on the side of your head (on both sides) and partly on the back of your head. The probes make contact with your skin, but they do not need to be glued or adhered in any way to your skin.

Once the recording probes are in place you will be presented with different situations, some will involve you watching a computer screen, some will involve listening and some will involve sensations on your index fingers. You will be given specific instructions at the time of testing with exactly what you will need to do in each case. At no time will any of the situations involve physical discomfort.

The fNIRS machine works by using light at specific frequencies to measure the amount of oxygen being carried in your blood. By analyzing the changes in the way oxygen is being carried in your blood we can determine the amount of activity of specific regions of your brain. We will play sounds and instruct you to do simple tasks like moving your eyes while recording. You may also feel small vibration sensations during testing as well. You should always feel free to ask questions about our experimental procedures. While measuring your brain's activity, the probes will emit low intensity near-infrared light, which is harmless.

Sound Testing - (20 minutes) This testing will involve you sitting inside a specialized room designed to reduce all outside noise. Sounds will then be generated from different speakers from inside the room and you will be asked to determine from which direction you heard the sound.

Questionnaires – (30 minutes) You will be asked to complete questionnaires related to different aspects of your hearing and how your hearing impacts your day-to-day functioning. Some will be completed before fNIRS testing, some will be completed after fNIRS testing.

Medical Record Review

As part of this research study, we are asking your permission to use your medical records to see if you are eligible to be in this study and to support the data collected in the study. This permission does not expire. We will collect the following information related to your hearing diagnosis: previous testing, surgeries and office visits. No results from the testing we do with you will be placed into your medical records held at UPMC. This medical record information, which includes your name, is available to members of the research team for an indefinite period.

Please note that Visits 1 and 2 can be completed in any order. Our research coordinator will work with you to schedule these visits at a convenient time for you.

*****If you are a Control subject:**

Your research participation will end after the completion of Visit 1 and Visit 2.

*****If you are an SSD subject:**

If you will NOT be receiving a cochlear implant for your SSD, your research participation will end after the completion of Visit 1 and Visit 2.

If you WILL be receiving a cochlear implant for your SSD, you will be asked to continue with the following 5 research visits:

VISIT 3 – fNIRS Testing Visit – (SSD subjects ONLY)

This visit will take place approximately *1 MONTH AFTER* the activation of the Cochlear Implant. The length of fNIRS visit will be approximately 2 TO 2.5 hours. Details of this visit are the same as Visit 2 above.

VISIT 4 – fNIRS Testing Visit – (SSD subjects ONLY)

This visit will take place approximately *3 MONTHS AFTER* the activation of the Cochlear Implant. The length of fNIRS visit will be approximately 2 TO 2.5 hours. Details of this visit are the same as Visit 2 above.

VISIT 5 – EEG Testing Visit – (SSD subjects ONLY)

This visit will take place approximately *3 MONTHS AFTER* the activation of the Cochlear Implant. The length of EEG testing visit will be approximately 3.5 hours. Details of this visit are the same as Visit 1 above.

***The order of Visits 4 and 5 can be switched if needed.

VISIT 6 – fNIRS Testing Visit – (SSD subjects ONLY)

This visit will take place approximately *6 MONTHS AFTER* the activation of the Cochlear Implant. The length of fNIRS visit will be approximately 2 TO 2.5 hours Details of this visit are the same as Visit 2 above.

VISIT 7 – fNIRS Testing Visit – (SSD subjects ONLY)

This visit will take place approximately *12 MONTHS AFTER* the activation of the Cochlear Implant. The length of fNIRS visit will be approximately 2 TO 2.5 hours. Details of this visit are the same as Visit 2 above.

What are the possible risks, side effects, and discomforts of this research study?

Risks associated with EEG testing visit: You may experience some minor skin irritation where the electrodes are placed. If you do, this irritation should be mild and not last very long. When the size of your pupils are being measured the research staff will ask you to keep your eyes open for longer than usual. This could lead to some eye irritation or discomfort. We will work with your

comfort and provide you with extra time to blink and get your eyes feeling comfortable before continuing the visit. During any of the EEG testing visit, you may become bored or become tired. If this happens, we will give you breaks and allow you to get up and move around to help to keep you focused.

Risks of fNIRS testing visit:

There is a minimal risk related to the fNIRS testing visit. There is a possibility that you may experience fatigue or discomfort during fNIRS recording. You will be given the opportunity to adjust your positioning to your comfort. The questionnaires that you will be asked to complete will be given to you several times during your participation in this research. You may experience boredom, fatigue or frustration when asked to complete them. The research staff will allow you to take breaks as needed to help you to focus during the sessions. At each fNIRS testing visit you will also be asked to complete the Sound Testing. This testing can cause boredom, fatigue or frustration. The research staff will work with you by permitting breaks throughout the visit.

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

Risks of collection and storage of your private health information

It is possible that your confidentiality may be breached, and your medical record information may be revealed to individuals not involved in this research. To protect your identity, research records, will be coded with a random ID number. The link between your name and your research code will only be available to a select group of researchers involved in this project.

Text messages and emails may not be encrypted or secure during their transmission or storage and it is possible they could be intercepted and used by others not associated with this study.

What are the possible benefits of taking part in this study?

You will receive no direct benefit from participating in this research study. Because of your participation, there may be advancement in our knowledge about SSD or there may be a potential future benefit to society.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you nor your insurance company will be billed for any part of this research study.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in his research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for an indefinite period after the final reporting or publication of a project.

Is my participation in this research study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in this research study.) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your doctor may be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

Will I be paid if I take part in this research study?

Yes, you will be paid for their participation. The amount of payment is based on the number of visits that you complete.

The study team will discuss the payment options with you. . Additionally, you will receive parking validation to cover the cost of parking at the Forbes Tower lot for each of these research visits.

Control Subjects: The maximum amount of payment that Control subjects can receive is $165. Control subjects will receive $125 for the completion of the EEG testing visit and $40 for the completion of the fNIRS testing visit.

SSD Subjects: The maximum amount of payment that SSD subjects can receive is $500.

SSD subjects who do NOT receive a cochlear implant will only have the opportunity to complete Visits 1 and 2.

You will receive $125 for the completion of the EEG testing visit and $40 for the completion of the fNIRS testing visit.

In this case, your maximum payment amount will be $165.

SSD subjects who DO receive a cochlear implant will have the opportunity to complete Visits 12 AND to complete Visits 3-7.

You will receive $125 for the completion of each EEG testing visit and $40 for the completion of each fNIRS testing visit.
There are 2 EEG testing visits (2x$125=$250). There are 5 fNIRS testing visits (5x$40=$200).
Participants will have the option to receive a $50 bonus for completing all study visits.
Maximum total payment of $500 if you complete visits 1-7.

Additionally, you will receive parking validation to cover the cost of parking at the Forbes Tower lot for each of these research visits.

Your data used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a "Form 1099 – Miscellaneous" with the IRS and provide a copy to the taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding; thus you would only receive 76% of the expected payment.

Who will know about my participation in this research study?
Any information you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this authorization (consent) form and

their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical record information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Authorized representatives of UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e., quality assurance).

We will protect the confidentiality of your records. This means we will keep your records secure and do all we can to prevent people who have not been given permission to be able to access it. We cannot guarantee the confidentiality of your information from this study, including from your medical records once people outside UPMC or the University have viewed it.

Will I know about new information related to this research study?
You will be promptly notified if, during the conduct of this research study, any new information is discovered that is clinically relevant to you.

Overall study results from the testing will not be provided to you directly. The information being collected is for research purposes and will have no clinical relevance to your care.

Who will have access to de-identified information related to my participation in this research study?
Portions of your health information and testing will be stored for an unlimited period of time to be used in future research. This information will not contain your identifiable information. Data in a de-identified manner may be shared with other researchers and with federal repositories after the necessary agreements have been executed.

May I withdraw, at a future date, my consent for participation in this research study? You may withdraw, at any time, your consent for participation in this research study, including your authorization to allow the research team to review your medical records; if you do so, you will no longer be permitted to participate in this study.

If you withdraw from the study, you will be able to withdraw consent from having your data previously collected used for the purposes of this study. If you decide to withdraw consent from the study but do not withdraw consent from having your data used and all collected survey data will continue to be used for the purposes of this study. No additional data will be obtained from the medical record after you withdraw from the study.

If I agree to take part in this research study, can I be removed from the study without my consent?

It is possible that you may be removed from the research study by the researchers if, for example, the study team feels that you are unable to consistently follow instructions during testing.

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VOLUNTARY CONSENT

The above information has been explained to me, and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns, or complaints be addressed by the listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the abovenamed individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no component of this research study was begun until after this consent document was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date