University of Pittsburgh

School of Medicine
Department of *Otolaryngology*

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Subjective and Somatic Tinnitus

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Source of Support: National Institute on Deafness and Other Communication Disorders

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.

Tinnitus, ringing in the ears, is a common problem that leads to changes in the brain. Using functional near infra-red spectroscopy (fNIRS) testing, we are now capable of identifying these changes in the brain related to tinnitus. fNIRS is able to measure brain activity of a specific part 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) to measure brain activity in this project. This research will help us to learn more about tinnitus changes in the brain and more closely compare information in two specific types of tinnitus (somatic and sensory tinnitus). Somatic Tinnitus is when the sound can change by moving your head or neck, or by opening and closing your jaw. This means if you can make the sound louder or softer or change its pitch by doing these movements. Sensory Tinnitus is the perception of sound such as ringing or buzzing when there isn't any other noise present.

- If you decide to participate in this research, you will be asked to complete up to 3 research visits. Today, we will collect your contact information so that we can schedule future visits. These future visits will involve the creation of molds of your ear canal, (approximately 30 minutes), completion of surveys/questionnaires related to tinnitus

(approximately 20 minutes), fNIRS testing (approximately 45 – 60 minutes) and Electroencephalography (EEG) testing (approximately 45-60 minutes). You may also have a hearing test to confirm that you qualify to participate (less than 30 minutes) 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.

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

Why is this research being done?
This research study is designed to look at information related to two different types of tinnitus. Information to be collected will include brain recordings using fNIRS and EEG technology as well as information collected from several questionnaires. Information will be collected from patients who have tinnitus and patients who do not have tinnitus (controls).

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, 25-70 years of age who is being seen by a member of the clinical team at Eye and Ear Institute for the evaluation of bilateral (both sides), non-pulsatile(constant), tinnitus. **OR** you are an adult, 25-70 years of age and were never diagnosed with any form of tinnitus. We are looking to enroll about 150 people overall (with tinnitus 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 – (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 this project will be completed in 3 visits or less. Depending on your availability and the availability of our study personnel, the enrollment visit, will include a hearing test and the Ear Mold Impression visit may be able to be combined into a single visit.

Visit 1 – You may need to undergo a hearing test to verify that you qualify for participation. If you have not already completed a recent hearing test as part of your clinical care, one will be completed as part of this research. During this test you will be asked to listen carefully to the various sounds you will hear once foam earphones are placed in your ears. You will then be asked to respond when you hear a sound and asked to repeat the words that you hear. We ask that you remain still and quiet during the testing. This will take under 30 minutes.

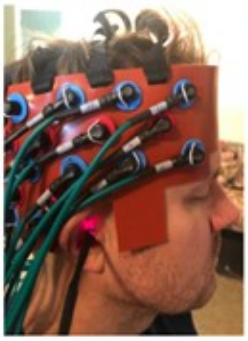
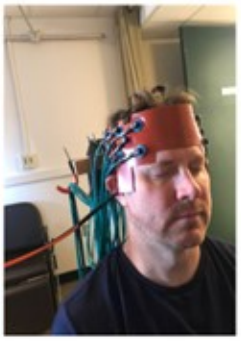
Ear Mold Impressions (less than 30 minutes)

You will be asked to report to the Fifth and Halket Building located at 3396 Fifth Avenue Pittsburgh, PA 15213 for the creation of ear mold impressions. These ear mold impressions will be made using the same materials involved in the creation of custom hearing aids. A trained audiology clinician will ask you questions as to whether or not you have had previous ear surgery that changed the shape of your ear canal and to learn if you are currently on blood thinning medication or have a bleeding disorder. They will then look in your ears to make sure there is no excessive wax or other debris that could be in the way of the earmold material. If excessive wax or other debris found, the study team will then remove it by gently scraping it out of the ear canal. Then, a cotton liner will be placed in your ear to protect your eardrum, and the molding putty will then be inserted into your ear using a medical syringe. The material in your ear will take about 5 minutes to harden and will then be carefully removed. The cotton liner will also be removed, and your ear will again be examined to make sure that all of the material has been removed. The reason for making these impressions is to create an accurate, 3D model of the structures inside your ear canal to be used to safely perform the fNIRS testing that we will discuss below. For your convenience, this visit can be completed on the day that you enroll in the study if time permits.

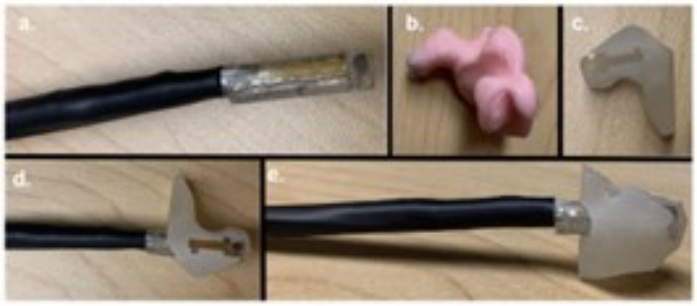
Once the 3D models of your ear canal have been created from your ear molds, you will be contacted to set up Visit 2. Visit 2 will take place at the Fifth and Halket Building located at 3396 Fifth Avenue Pittsburgh, PA 15213

Visit 2 – (to be scheduled approximately 2-6 weeks after Visit 1) (approximately 2.5-3 hours)
Surveys (less than 30 minutes):
You will be asked to complete several questionnaires that will give us more information about your personal health, and your hearing health quality.

fNIRS testing (45-60 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 also 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. Your custom 3D ear pieces will then be inserted in each of your ears. There are 2 specific probes that will then be positioned inside your ear by an experienced researcher.



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.
If you have somatic tinnitus, you will be asked to recreate positions the cause your tinnitus.
During the testing described above you may also feel small vibration sensations.
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. The light from the probes will not harm your ear drum or any other structures. We will ask you to sit as still as possible while we record your brain's activity with fNIRS.
After completion of the fNIRS testing, the fNIRS testing headgear and probes will be removed and you will be given a 15-minute break.

EEG testing (45-60 minutes)
The EEG testing cap/headgear will then be positioned on your head. The electrodes on the cap will not need to be glued to your head or scalp in any way. We will again play sounds, instruct you to do simple tasks and you may possibly feel small vibrations, the same way you will have done during the fNIRS recording. We will again ask you to sit as still as possible while we record your brain's electrical activity.

After the completion of the EEG testing, we will remove the EEG recording cap.

Surveys (5-7 minutes)
At the end of your visit, we will ask you to complete 2 more surveys. You will have completed these same surveys at the beginning of your visit. We would like to see how your opinions have changed after undergoing the testing.

A study team member will reach out to you after completion via phone call to see how you're feeling after undergoing research activities.

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 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.

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

Risks of Ear Mold Impressions:
There is a rare risk of minor discomfort during the process of creating your ear molds. You will have the process explained to you before the process begins. Any discomfort related to the pressure to insert the molding clay in your ear for the impression will be temporary. Also, there is a rare risk of minor bleeding due to the material scraping the inside of your ear when being removed. In most cases this will stop immediately. If the bleeding continues, we will direct you to follow up with your primary care physician.
In extremely rare cases, the mold material could seep past the cotton liner/block and make contact with the eardrum and cause damage to the eardrum. In this case, medical attention from and Ear, Nose and Throat provider will be arranged immediately. Surgery could be required to repair the eardrum or permanent hearing loss could occur. Please know that all safety precautions will be taken and your earmold will only be performed by a trained professional in this area. This type of complication, in a normal ear canal, has not been documented in our offices in over 30 years.

Risks of Audiometric Testing
While audiogram testing is a safe and non-invasive procedure, the following potential risks or discomforts may occur: Temporary discomfort from headphones or insert earphones, some individuals may experience slight pressure or discomfort from the equipment placed over or in the ears, mild anxiety or frustration particularly for individuals who are anxious about their hearing or find the test difficult, responding to tones can occasionally cause stress or frustration, brief ringing in the ears (temporary tinnitus): Rarely, exposure to test tones may trigger mild ringing in the ears, especially in individuals with existing sensitivity, fatigue or inattention: testing typically requires sustained focus in a quiet environment, which can be tiring for some individuals, especially children or those with attention difficulties, claustrophobia (if performed in a sound booth) some individuals may feel confined or anxious in the testing environment.

Risks of fNIRS recording

There is a minimal risk related to the fNIRS probe recording inside of your ear. We are minimizing this risk by creating a 3D model of your ear so that the device will not come in direct contact with the small structures of your ear.

There is a possibility that you may experience fatigue or discomfort during the testing. You will be given the opportunity to adjust your positioning to your comfort.

You may experience a vibration sensation as part of the testing process. This vibration will be for a short period of time and should not cause you any discomfort. You will be told about the sensations that you will be experiencing at the time of testing.

The light being used is "low intensity, near infra-red" light and will not cause harm to you or thestructures of your ear.

Risks of EEG recording

There are minimal risks related to the EEG recordings. The primary risk is discomfort related to the EEG electrode cap placed on your head. We will work with you to find a comfortable position for this cap.

You may also experience fatigue or discomfort during the testing. You will be given the opportunity to adjust your positioning to your comfort.

You may experience a vibration sensation as part of the testing process. This vibration will be for a short period of time and should not cause you any discomfort. You will be told about the sensations that you will be experiencing at the time of testing.

Risks of completing the surveys/questionnaires

There is the possibility that the nature of some of the questions asked on the survey may be upsetting to you. It is also possible that you may become tired when completing the survey. We ask that you complete as many of the questions as you can, to provide us as much detail as possible. You can take as much time as you need to complete the surveys.

Risks of study participation

It is possible that you may experience a change in your tinnitus symptoms after the completion of your study participation. This may or may not be directly related to your participation in this study. If you experience a change in your symptoms, we ask that you reach out to the study coordinator at 412-952-7546 so that we can review the change and determine if additional steps are needed.

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.

Risks of text messages and email transmission.

Text messages 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. Emails may not be encrypted during transmission or storage and may 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 tinnitus or there may be potential future benefits 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?
You will be paid $80 in total for participating. The first payment of $40 will be made upon completion of the fNIRs recording. You will then receive an additional $40 payment upon completion of the EEG recording. You will also be provided with a voucher to cover parking costs for your time.

If it is determined that you do not qualify for full participation in the study due to your hearing testing, you will receive $20 for your time as well as a parking voucher, if appropriate. You will not be eligible to continue your participation and receive the full payment amount.

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.

Who will know about my participation in this research study?

Any information about 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).

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate 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 action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings; if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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.

Authorized representatives of the sponsor of this research study, National Institutes of Health may review and/or obtain identifiable information related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data.

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 performed 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 uncomfortable during testing or if 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