BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC

New York University & New York Eye and Ear Infirmary of Mount Sinai
SUBJECT INFORMATION AND INFORMED CONSENT FORM

Protocol Title: Sensory Integration of Auditory and Visual Cues in Diverse Contexts given Age, Vestibular Hypofunction and Hearing Loss
Protocol #:
Sponsor: National Institutes of Health

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KEY INFORMATION ABOUT THIS RESEARCH STUDY

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

You are being asked to be a subject in a research study because you have hearing loss OR dizziness related to the inner ear OR you are a healthy control.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	This is a research study to evaluate the contribution of what we hear to our ability to balance ourselves.
Experimental/ Investigational	Your balance will be tested while you are wearing a virtual reality headset. Within the virtual environments, you will experience different visuals and sounds.
Voluntary Participation	Your decision to participate in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	Your participation is expected to last up to 1 month. During that time you will have 2-4 study visits. [You can choose whether you prefer 2 longer sessions or 4 shorter sessions. The total number of hours is expected to be 5.]
Procedures	The main procedures in the study include: A hearing test and a test of how well your inner ear is working. A balance test with a virtual reality headset.

	The study clinicians will explain which procedures are being done for research and which would be done as part of your standard care, even if you chose to not participate.
Risks	The risks associated with this study are minimal. Possible side effects during testing may include nausea, increased dizziness, and imbalance.
Benefit	There is no direct benefit to you from taking part in this study.
Costs	The study sponsor will pay for the cost of all procedures that are required for the study. You will receive a $25 pre-paid debit card for each session.
Confidentiality	There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information.

This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS

The National Institutes of Health, the sponsor of this study, is providing funds to New York University and the New York Eye and Ear Infirmary of Mount Sinai for conducting this research study.

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

PURPOSE OF THE STUDY

The purpose of this study is to identify why people with inner ear problems and hearing loss may have balance problems.

NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION

About 150 subjects are expected to participate in this study at 2 research sites in the United States.

Your participation in this study is expected to last 1 month.

STUDY PROCEDURES

If you agree to participate in this research study, the following information describes what may be involved.

- A session where you will have a hearing test and inner ear test performed by an audiologist at the Ear Institute. This is a standard battery to assess how well the inner ear is working for balance and includes:

    - A test while wearing goggles that allows careful monitoring of eye movement in response to hot and cold air placed in the ear canal by the audiologist.
    - A test while wearingsticker electrodes on your neck or eye muscles that record responses to loud clicks or sounds played in each ear.
    - Audiogram (hearing test): You will wear headphones and be asked to identify sounds at different frequencies and repeat simple words.
    - Another tests with goggles and in which you focus on a target on the wall. The audiologist will move your head right, left, up, down, and diagonal while you keep your eyes on the target.
    - A quick screen of your vision and sensation at the bottom of your feet.
    - The tests are expected to take 2- 2 ½ hours and can be performed in 1 or 2 sessions.

- An assessment of balance for which you will do the following:

- Complete several questionnaires about your demographics, dizziness, balance confidence, and anxiety.
- Complete tests of walking and balance with and without virtual reality
- Stand on a force platform while wearing a virtual reality headset, observing different scenes and listening to sounds. While you're doing that, we will record your movements under your feet, your head movements and your eye movements. We are not recording a video of you.
- Sounds will be played at the highest level that is comfortable to you.
- The balance tests are expected to take up to 2- 2 ½ hours and can be performed in 1 or 2 sessions.

Clinically Relevant Results
If results of study procedures (e.g. vestibular, hearing testing) give clinical information that may be important to your health care, you will be informed about those results.

SUBJECT RESPONSIBILITIES
As a subject in this study, you will have certain responsibilities, including the following:

- Attend all study visits and, if needed, reschedule appointments as soon as possible
- Follow the instructions of the study team
- Tell the study key personnel all medications that you are taking
- Tell the study staff any time you do not feel well
- For testing of the inner ear, no caffeine or alcohol or taking medication related to dizziness (if that is your complaint) or that may affect dizziness 24 hours prior to the test.
- Do not drink alcohol 24 hours prior to balance testing.

RISKS AND DISCOMFORTS
Possible side effects during testing (during all sessions, but more likely during the diagnostic testing than during balance testing) may include nausea, vertigo (dizziness), increased dizziness, and imbalance. We previously reported minimal cybersickness in healthy young adults, patients with vestibular dysfunction, and age-matched controls. Nevertheless, because of this possibility, we will be repeatedly asking you about your symptoms and will make sure you are doing well during the session as well as before you leave the lab when the session ends. If you experience any discomfort, you will be given rest breaks, or if necessary, the session will be discontinued. If this happens, you will be asked to wait with the researchers until symptoms subside. Typically, any discomfort subsides in 20-30 minutes. In addition, you may have a buzzing in the ears. Common techniques to facilitate recovery from dizziness include continuous walking or sitting with head supported. These techniques will be used to facilitate symptom recovery if necessary. During the balance testing, it is possible that you will feel as if you are losing your balance. Your risk of falling is no more than minimal because a physical therapist or a trained student will be standing next to you and guarding you throughout the procedure. There will also be canes placed by your sides. All of these constitute minimal risks.

You may feel uncomfortable answering questions about your balance confidence, disability or anxiety levels. You can choose to leave answers blank on the self-reported questionnaires. It is possible that the virtual reality environments will reproduce transient feelings of anxiety similar to what you may experience in daily living. We will provide rest breaks as needed. You can stop the test at any time. You can ask to avoid testing within any of the environments.

Risk of loss of private information; this risk always exists, but, there are procedures in place to minimize the risk.

The information collected as part of this study involves no more than minimal risk and will not compromise your privacy and/or welfare. Any identifiable information will be removed by assigning ID numbers to each participant. Only de-identified data will be entered into a password-protected database. The data form(s) to be utilized for the purpose of collecting specific data will not contain any identifiable information. Data will be stored on password-protected computers in a limited access building. Personal identifying data will be kept separate from the data, and data will be stored in an encrypted format. Only key study personnel will have exclusive access to the data throughout the study.

CLINICALTRIALS.GOV
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

NEW INFORMATION
You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

BENEFITS
There is no guarantee that your condition will improve as a result of your participation in this study. It may stay the same or worsen. However, the information learned from this study may help other people with balance problems in the future.

ALTERNATIVES TO STUDY PARTICIPATION
You do not have to participate in this study to receive treatment for your condition. The study clinician will discuss study alternatives with you and their risks and benefits.

COSTS OF PARTICIPATION
There is no additional cost to you for your participation in this study.

You and/or your insurance company will be responsible for the costs of all items and services during the research study, which you would have received for your condition if you were not enrolled in this research study and/or that your physician believes are medically necessary to treat you.

REIMBURSEMENT
You will receive $25 for each visit. If you leave the study early, you will be reimbursed only for visits you complete. You will be reimbursed by pre-paid debit card at the completion of each study visit.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS). Generally this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

COMPENSATION FOR INJURY
If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including

deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

For medical emergencies please call 911.

No other compensation will be offered by New York University or New York Eye and Ear Infirmary of Mount Sinai or the sponsor or the Biomedical Research Alliance of New York.

You are not waiving any legal right to seek additional compensation through the courts by signing this form.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?
As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, dates directly related to the individual (birth, admission, discharge, etc.), e-mail addresses, and medical records number.

The researchers will also get information from your medical record from the Mount Sinai Health System including your doctor at the Ear Institute at New York Eye and Ear Institute of Mount Sinai and your primary care doctor.

During the study the researchers will gather information by:

- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.) and obtaining results from diagnostic and medical procedures including but not limited to x-rays
- doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System (“Mount Sinai”) workforce may use and share your information to ensure that the research meets legal,

institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: New York University
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: National Institute of Health
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration
- The United States Department of Health and Human Services and the Office of Human Research Protection
- Others: Biomedical Research Alliance of New York (BRANY) and the Icahn School of Medicine at Mount Sinai Institutional Review Board, Department of Health and Human Services Agencies, Governmental agencies in other countries, Accrediting agencies, and Health insurers and payers.

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information? Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

NOTICE CONCERNING HIV-RELATED INFORMATION
HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights or New York City Commission on Human Rights. These agencies are responsible for protecting your rights.

CERTIFICATE OF CONFIDENTIALITY

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your research information or biospecimens with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

USE OF YOUR DATA AND/OR SPECIMENS

In the future, your identifiable information may be removed from the private information and/or samples that are collected as part of this research. After this removal, the information and/or samples could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information and biospecimens. That means that a research project might be done that you would not consent to if provided with the details of that research project.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study doctor.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the study doctor's office for a final study visit for your safety.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS
If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Anat Lubetzky at 212-998-9195 or Bryan Hujsak at 646-438-7871.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

PHOTOS
We are asking your permission to take photos of you wearing the headset (i.e. with your eyes covered) and record a video of you performing the tasks. You may review these tapes and request that all or any portion of the tapes be destroyed. With your permission, the photos could be used for publications and presentation of the results. Initial next to your choice below . You can still participate in the study if you do not check these boxes and we will not take any pictures / videos of you.

_____I agree to have pictures of me taken
_____I do not agree to have pictures of me taken

_____ I agree to be videotaped
_____I do not agree to be videotaped

STATEMENT OF CONSENT
By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

Subject: Name (Print)	Signature	Date
Person Obtaining Consent: Name (Print)	Signature	Date