

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: *Multisensory convergence mapping to multimodal output in vestibular disorders (STU 00207270)*

Consent version: 2019-01-18-09-03

Consent version date: 01/18/2019

Principal investigator: *Marcello Cherchi, MD, PhD*

Supported by: This research is supported by Northwestern University, though is not funded by Northwestern University or by any other source.

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: The study investigators have no conflicts of interest to disclose.

Your right to discuss your participation in this study with others: Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because ***of your symptoms of dizziness, or imbalance, or unsteadiness, or any other perceived disturbances of equilibrium. The physicians at Chicago Dizziness and Hearing are on staff at an academic medical center (Northwestern Memorial Hospital), thus part of our mission involves conducting research on balance and hearing disorders.***

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Where is this research being done?

This research is being done at Chicago Dizziness and Hearing.

Why is this research being done?

Purpose of research: The purpose of this study is to analyze patterns among the results of a number of tests of your hearing and balance function.

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Background of research problem: The various tests of hearing and balance function sometimes give apparently conflicting results. We are interested in whether these apparent conflicts are due to differences among the tests themselves, or differences in the diseases they are intended to detect.

Potential benefits: Understanding these tests better may help improve their accuracy in diagnosis, or develop new tests that do a better job.

FDA approval: The tests are all FDA approved. None of the tests is experimental or investigational.

How long will the research last and what will I need to do?

This research will be ongoing for several years. However, **the duration of your participation in the study will be limited to the time required for the diagnostic tests**. The length of time varies because the selection of the specific diagnostic tests will depend on which illness you have (or are suspected to have). The shortest amount of time would be approximately four minutes. The longest amount of time would be approximately six hours. Despite this broad range, the average duration of testing is generally in the range of 90 minutes to 3 hours. Depending on scheduling availability, equipment and staff, the tests can often be completed during a single calendar day. In some instances it may be necessary to distribute the tests over 2 calendar days (not necessarily consecutive).

During this research you will be asked to undergo several assessments. This generally includes a physical examination, and may also include tests of eye movements, hearing, and balance function. The tests of hearing, eye movements and balance function are all FDA-approved; none of the tests is experimental or investigational.

The research itself does not involve studying a particular medication. The research itself does not require obtaining any blood or tissue samples. The research itself does not require any hospitalization.

More detailed information about the study procedures can be found under the section, **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

Your participation in this study may involve the following risks:

Vestibular evoked myogenic potentials: In rare instances, some people experience skin irritation from the cleanser used before electrode application.

Videonystagmography and rotatory chair testing: In rare instances (approximately one percent of individuals) there are sections of each test that can provoke nausea or vomiting.

Video Frenzel oculography: In very rare instances (less than one tenth of one percent of individuals), one section of this test (the Dix-Hallpike maneuver) can provoke nausea or vomiting.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)."**

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Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include that advancing our understanding of what these tests assess, we may be able to improve their accuracy in diagnosis, or eventually develop new tests that do a better job.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate. The choice not to participate will not affect the medical care that you receive.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

Principal Investigator's Name: Dr. Marcello Cherchi, M.D.
Institution: Northwestern University Feinberg School of Medicine
Department: Neurology
Address: 645 N. Michigan Ave. #410, Chicago, IL 60611

This research has been reviewed and approved by Northwestern's Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 1500 people here will be in this research study.

What happens if I say "Yes, I want to be in this research"?

As mentioned earlier, there are a number of tests or examination maneuvers/techniques that may be recommended; the specific tests will be selected based on your history and which diagnoses are being considered. **Not every patient requires every test.** Below is a brief description of each diagnostic procedure, including what it tests, who performs the test, how long it takes, whether it needs to be repeated, what equipment it involves, what happens during the test, whether the test involves recording of any audio or video, and the format of the test results. A preliminary selection of the diagnostic tests applicable to your case will be made at or

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by the time of your first encounter with the clinician. Examples of which tests are appropriate for which diagnosis are listed in the table at the end of this document.

1. **Physical examination.** This is appropriate for most patients. This is not a “test” in the usual sense of that word — rather, it is a series of physical examination techniques conducted by a clinician (physician or physical therapist, depending on the medical encounter). The specific physical examination techniques will be decided by the clinician during your visit, based on your history and the diagnoses being considered. The duration of the physical examination depends on which specific examination techniques are selected; in general the physical examination can last from 10 to 25 minutes. The physical examination may be repeated at subsequent visits.
2. **Audiometry.** The purpose of audiometry is to assess certain aspects of hearing ability. This is appropriate for some (but not all) patients, depending on the medical history and the diagnoses being considered. This is a standardized hearing test that is FDA-approved; it is not experimental or investigational. Audiometry is performed by a trained technician at Chicago Dizziness & Hearing. An audiogram takes about 20 to 30 minutes. The test is usually only performed once, though in some instances may be repeated. The equipment involved in this test includes a soundproof booth, earphones (which may be either headphones or earbud insert earphones), a response keypad, and a computer which sends sounds to the earphones and records your responses from the keypad. During the test you will be seated in the soundproof booth; you will hear a variety of sounds and/or words through headphones; you will push buttons or hold up your hand to indicate that you have heard the sound, or you will repeat the words that you heard back to the technician. The test does not involve recording of any audio or video. The test result is a graph representing hearing sensitivity in each ear. Audiometry is part of this research study. Your participation is optional.
3. **Otoacoustic emissions (OAEs).** The purpose of OAE is to assess certain aspects of hearing ability. This is appropriate for some (but not all) patients, depending on the medical history and the diagnoses being considered. This is a standardized hearing test that is FDA-approved; it is not experimental or investigational. The OAE test is performed by a trained technician at Chicago Dizziness & Hearing. Testing OAEs takes about 10 – 15 minutes. The test is usually only performed once, though in some instances may be repeated. The equipment involved in this test includes a soundproof booth; you will be wearing ear-insert earphones; you may or may not hear soft, high-pitched sounds. The test does not involve recording of any audio or video. The test result is a chart or graph depicting hearing ability. The OAEs test is part of this research study. Your participation is optional.
4. **Video Frenzel oculography (VFO).** The purpose of the VFO is to measure eye movements, that in turn reveal information about the balance functions of the inner ear and brain. This is appropriate for some (but not all) patients, depending on the medical history and diagnoses being considered. This is a standardized oculomotor test that is FDA-approved; it is not experimental or investigational. The VFO is performed by a physician, physical therapist or trained technician at Chicago Dizziness & Hearing. The VFO test takes about 5 – 10 minutes. The equipment involved in this test includes a set of goggles (similar to a SCUBA mask) that is secured to your head by a strap; an eye occluder that is sometimes closed so that you feel you are in complete darkness; a tiny camera in the goggles that monitors your eye movements; sometimes an LED or screen in front of you that may display images or a target for you to follow with your eyes; and small wires that bring the movie of your eyes to a computer where the video is processed. During the test the examiner may instruct you to move your head or body

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into specific positions. The test does not involve recording of any audio. The test does involve video recording; specifically, your eye movements are recorded in digital format; in some cases a video of your body is also recorded (simply so that we can determine your body position during various eye movements). The result of the test is video of the eye movements, that in some cases may be analyzed and depicted in a graph. The VFO is part of this research study. Your participation is optional.

5. **Vestibular evoked myogenic potentials (VEMPs).** The purpose of VEMP testing is to assess parts of the inner ear balance organ. This is appropriate for some (but not all) patients, depending on the medical history and the diagnoses being considered. This is a standardized vestibular test that is FDA-approved; it is not experimental or investigational. The VEMP test is performed by a trained technician at Chicago Dizziness & Hearing. The VEMP test takes about 45 to 60 minutes. The test is usually only performed once, though in some instances may be repeated. The equipment involved in this test includes a device that generates sounds; ear insert headphones that deliver the sound to your ears; electrodes that are applied to the skin over various muscles that detect signals of muscle activity; wires that transmit those signals to a receiver; and a device that collects those signals. The test is usually performed only once, though in some instances may be repeated. During the VEMP test your skin will be cleaned and surface electrodes will be temporarily secured to your skin in several places using a type of paste and tape; the electrodes may be placed on the neck, arms, legs, or head (near the temples, on the forehead, or above and below the eyes); you will wear headphones or earbud insert earphones; you will listen to a series of clicks or tones through the headphones or earbud insert earphones; in some cases, we will also apply small electrical impulses using surface electrodes; in some other cases, we will also be presenting a visual stimulus in the form of stationary or flashing lights using a free-standing light source. The VEMP test does not involve any recording of audio or video. The results of the VEMP test consist of a series of digitized waveform tracings representing muscle activity. The VEMP test is part of this research study. Your participation is optional.
6. **Video head impulse testing (vHIT).** The purpose of the vHIT is to measure certain eye movements, that in turn reveal information about the balance functions of the inner ear and brain. This is appropriate for some (but not all) patients, depending on the medical history and the diagnoses being considered. This is a standardized vestibular test that is FDA-approved; it is not experimental or investigational. It is performed by a trained technician at Chicago Dizziness and Hearing. The vHIT takes about 20 minutes. The test is usually only performed once, though in some instances may be repeated. The equipment involved in this test includes a set of goggles (similar to swim goggles) that is secured to your head by a strap; the goggles contain a tiny camera that monitors your eye movements; the video from that camera is transmitted along small wires to a computer; the computer processes and records those eye movements. During the test the technician will hold your head, and direct your head through small, quick movements while you focus on a visual target directly ahead of you. The test does not involve audio recording. The test does involve video recording; specifically, a video of only your eyes (not your head or body) is recorded in digital format. The result of the test is a series of graphs representing the eye movements. The vHIT is part of this research study. Your participation is optional.
7. **Videonystagmography (VNG).** The purpose of this test is to measure certain eye positions and movements, that in turn reveal information about balance function of the inner ear and brain. This is appropriate for some (but not all) patients, depending on the medical history and the diagnoses being considered. This is a standardized vestibular test that is FDA-approved; it is not experimental or investigational. It is performed by a

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trained technician at Chicago Dizziness and Hearing. The VNG takes about 45 to 60 minutes. The test is usually only performed once, though in some instances may be repeated. The equipment involved in this test includes a set of goggles (similar to a SCUBA mask) that is secured to your head by a strap; an eye occluder that is sometimes closed so that you feel you are in complete darkness; a tiny camera in the goggles that monitors your eye movements; an LED or screen in front of you that may display images or a target for you to follow with your eyes; small wires that bring the movie of your eyes to a computer where the video is processed; an irrigator that (in some cases) will put warm and cool water or air into each ear at different times. The test does not involve audio recording. The test does involve video recording; specifically, a video of only your eyes (not your head or body) is recorded in digital format. The result of the test is a series of graphs representing the eye movements. The VNG is part of this research study. Your participation is optional.

8. **Rotatory chair testing (RCT).** The purpose of this test is to measure certain eye positions and movements, that in turn reveal information about balance function of the inner ear and brain. This is appropriate for some (but not all) patients, depending on the medical history and the diagnoses being considered. This is a standardized vestibular test that is FDA-approved; it is not experimental or investigational. It is performed by a trained technician at Chicago Dizziness and Hearing. The RCT takes about 45 to 60 minutes. The test is usually only performed once, though in some instances may be repeated. The equipment involved in this test includes a set of goggles (similar to a SCUBA mask) that is secured to your head by a strap; an eye occluder that is sometimes closed so that you feel you are in complete darkness; a tiny camera in the goggles that monitors your eye movements; an LED or screen in front of you that may display images or a target for you to follow with your eyes; small wires that bring the movie of your eyes to a computer where the video is processed; a rotatable chair in which your body and head are secured (by small straps), and the chair rotates gently in a variety of patterns. The test does not involve audio recording. The test does involve video recording; specifically, a video of only your eyes (not your face or body) is recorded in digital format. The result of the test is a series of graphs representing the eye movements. The RCT is part of this research study. Your participation is optional.
9. **Electrocochleography (ECoG).** The purpose of this test is to assess certain characteristics of the inner ear hearing and balance organs, such as their pressure. This is appropriate for some (but not all) patients, depending on the medical history and the diagnoses being considered. This is a standardized vestibular test that is FDA-approved; it is not experimental or investigational. It is performed by a trained technician at Chicago Dizziness and Hearing. The ECoG takes about 45 to 60 minutes. The test is usually only performed once, though in some instances may be repeated. The equipment involved in this test includes a set of small electrodes connected to wires that in turn connect to a computer; and earbud insert earphones connected to a computer. During the test the electrodes are placed in specific positions in the ear canal and in several areas of the head and neck; those electrodes on the head and neck are secured using a type of paste and tape; earbud insert earphones are then placed in the ear; you will hear a series of pulsed tones; the electrodes pick up tiny signals and send them through wires to a computer. The test does not involve audio or video recording. The result of the test is a series of graphs representing particular characteristics of the inner ear. The ECoG is part of this research study. Your participation is optional.
10. **Computerized dynamic posturography (CDP).** The purpose of this test is to quantify overall balance ability and (in some cases) to characterize the possible reasons for imbalance. This is appropriate for some (but not all) patients, depending on the medical history and the diagnoses being considered. This is a standardized vestibular test that is

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FDA-approved; it is not experimental or investigational. It is performed by a trained technician at Chicago Dizziness and Hearing. The CDP test takes about 20 – 25 minutes. The test is usually only performed once, though in some instances may be repeated. The equipment involved in this test includes a phone-booth-sized chamber whose floor may or may not move and whose walls may or may not move; a blindfold that may or may not be applied; a harness that prevents a patient from falling; and a computer that controls the movements of the booth's floor and walls and also monitors the patient's sway pattern. During the test you will be secured in the harness so that you do not fall; you will go through a series of test scenarios with different conditions (sighted or blindfolded; the floor moving or not moving; the walls moving or not moving); in some instances you may be looking at a screen displaying various patterns. The test does not involve audio or video recording. The result of the test is a series of graphs representing the sway patterns of your body during the different testing conditions. The CDP is a part of this research study. Your participation is optional.

11. **Retinal imaging.** The purpose of this test is to measure certain eye positions and movements, that in turn reveal information about balance function of the inner ear and brain. This is appropriate for some (but not all) patients, depending on the medical history and the diagnoses being considered. These are standardized ophthalmological imaging tests that are FDA-approved; they are not experimental or investigational. Depending on equipment availability, these tests will be performed either at Chicago Dizziness and Hearing, or you will be referred to the Department of Ophthalmology at Northwestern. Retinal imaging takes about 10 minutes. The test is usually only performed once on each eye, though in some instances may be repeated. These techniques involve taking a picture of the retina (the back of the eye). The tests do not involve the use of dilating eye drops. During the test your chin is leaning on a small chinrest and your forehead is leaning up against a small head frame; in some instances the head may need to be stabilized with additional equipment to insure proper positioning while the retinal images are acquired. The tests are performed by a trained technician. The tests do not involve any audio recording; the test does involve acquiring individual images, or a series of images (video), of the retina (the back of the eye). There are two standard retinal imaging technologies (both of which are FDA-approved) that are used for this purpose: optical coherence tomography (OCT) and retinal photography; the choice of which test to use may depend on features of your medical history. The result of the test is a set of pictures and graphs representing specific anatomical features of the retina of each eye, and positions or movements of the eye. The retinal imaging is part of this research study. Your participation is optional.

The procedures described above do not require that you take any medications; nor do they require you to stop any of your current medications; nor do they require you to change the doses of any of your current medications.

This study does not require hospitalization.

This study does not require any blood samples to be drawn.

The study does not require any tissue samples to be taken.

In some cases we may contact you for future research in this study; your participation is optional.

This research involves study of diagnostic techniques. It is not a study of any specific treatments; therefore there is **no** "randomization," there is **no** "treatment group" or "placebo group," and there is **no** "blinding" of results.

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The results of the tests described above will be stored in your medical record, and a copy will be provided to you.

What are my responsibilities if I take part in this research?

This study is **not** a clinical treatment trial. Therefore, your responsibilities, if you choose to participate in the study, include undergoing the tests described earlier. Your participation in the study is optional. Your decision (whether to participate or not participate) in the study will not affect your medical care.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time it will not be held against you.

If you decide at any point to withdraw from the research, please inform the investigators either in person, or in writing, or by email, or by telephone. You do not need to cite any specific reason for your choice to withdraw from the study. If you withdraw from the research, no additional study information will be collected about you.

Choosing not to be in this study, or choosing to stop being in this study, will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study, or your choice to withdraw from the study, will not negatively affect your right to any present or future medical treatment, and will not affect your right to participate in any future research.

If you stop being in the research, the information already collected may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled in the same way as research data.

Detailed Risks: Is there any way being in this study could be bad for me?

Your participation in this study may involve the following risks:

In rare instances during testing vestibular evoked myogenic potentials, some people experience skin irritation from the cleanser used before electrode application. If your skin does become irritated, you will be asked whether you would like to discontinue the test or continue with the study. If you choose to continue, you may have redness where the electrode is attached for one to two hours after the electrode is removed. If you withdraw from the study, no more information will be collected from you for the study. You may withdraw at any time. Your participation in the study is optional.

Videonystagmography and rotatory chair testing: In rare instances (approximately one percent of individuals) there are sections of each test that can provoke nausea or vomiting. If this occurs, the test will be stopped, and you will be allowed to recuperate. At this point you will be asked whether you are willing to continue the test. If you are willing to continue the test, then we will offer you the anti-emetic agent ondansetron (unless you have a known allergy to ondansetron or are currently taking other medications that would pose a risk of significant interactions with ondansetron). If you decide not to continue, then the test will be aborted.

Video Frenzel oculography: In very rare instances (less than one tenth of one percent of individuals), one section of this test (the Dix-Hallpike maneuver) can provoke nausea or vomiting. If this occurs, the test will be stopped, and you will be allowed to recuperate. At this

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point you will be asked whether you are willing to continue the test. If you are willing to continue the test, then we will offer you the anti-emetic agent ondansetron (unless you have a known allergy to ondansetron or are currently taking other medications that would pose a risk of significant interactions with ondansetron). If you decide not to continue, then the test will be aborted.

This study involves the use of your identifiable, personal information and, despite the best efforts of everyone involved, there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **“What happens to the information collected for the research?”**

What do I need to know about reproductive health and/or sexual activity if I am in this study?

Participation in this study and its tests is not known to incur any risks, nor is there any literature that would lead to suspicion of any risk, to nursing women, to pregnant women, to women of child-bearing potential, to an embryo or to fetus. Participation in this study is not a contraindication to becoming pregnant or to nursing.

Will it cost me anything to participate in this research study?

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

All of the tests are FDA approved; none of them is experimental or investigational; they will be billed identically to when the tests are performed for patients not participating in the study. None of the tests is paid for by the study itself. You and your health insurance company will be charged for the health care services that you would ordinarily be responsible to pay. Before undergoing any testing, you should check with your health insurance company to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

There are no direct benefits to you from participation in this study. Since the outcome of this research is not predetermined, we cannot predict or promise any benefits to you or others from your taking part in this research. If the ultimate results of this study lead to improvement in the diagnostic tests available for the evaluation of vestibular disorders, then it is possible that this research will advance diagnostic accuracy in future patients with disorders of balance.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. Despite the best efforts of everyone involved, we cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB (institutional review board), other representatives of Northwestern University, and Chicago Dizziness and Hearing.

Since the tests are all FDA-approved, non-experimental and non-investigational, the results will become part of the patient's medical record, which is stored securely and indefinitely at Chicago Dizziness and Hearing, and will be accessible by the study investigators.

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Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include (but are not limited to) falsification (by the patient/study participant) of medical information.

What else do I need to know?

If you become ill or get injured as a result of this study (devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The researchers will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

As mentioned earlier, participants do not receive payment for participation in the study. Moreover, participants will be reimbursed neither for transportation nor for the time spent participating in the study.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires
- Records about medication or drugs
- Records about study devices
- Billing information
- Any information regarding substance abuse already contained in your medical record.
- Any genetic health information already contained in your medical record.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

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Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy.

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- Also, Federal Confidentiality Rules, 42 CFR Part 2, prohibit making any further disclosure of substance use disorder information unless further disclosure of this information is expressly permitted by written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Principal Investigator's Name: Dr. Marcello Cherchi, M.D.
Institution: Northwestern University Feinberg School of Medicine
Department: Neurology
Address: 645 N. Michigan Ave. #410, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, if you choose not to authorize disclosure of your health information, then you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree I disagree

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I agree

I disagree

The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.

The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.

The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

Signature Block for Adult Unable to Consent:

Your signature documents your permission for the named participant to take part in this research.

Printed Name of Participant

Signature of Legally Authorized Representative

Date

Printed Name of Legally Authorized Representative

Date

Signature of Person Obtaining Consent

Date

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Printed Name of Person Obtaining Consent

Date

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Test selection protocol

	VFO	Audio	OAE	BAER	cVEMP	oVEMP	vHIT	VNG	RCT	OCT or fundus photo	ECoG	CDP
Otologic												
Auditory neuropathy		√	√	√							√	
Autoimmune inner ear disease		√	√		√	√	√	√	√		√	√
Benign paroxysmal positional vertigo	√				√	√	√	√				√
Bilateral vestibular weakness	√				√	√	√	√	√			√
Congenital otologic malformation, such as EVA		√		√	√	√	√	√	√			√
Labyrinthine concussion		√										
Ménière's	√	√			√	√	√	√			√	√

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	VFO	Audio	OAE	BAER	cVEMP	oVEMP	vHIT	VNG	RCT	OCT or fundus photo	ECoG	CDP
Otosclerosis	√	√	√		√	√	√	√	√		√	√
Ototoxicity		√	√	√	√	√	√	√	√		√	√
Perilymphatic fistula		√	√		√	√					√	√
Superior canal dehiscence	√	√	√		√	√	√	√			√	
Temporal bone fracture		√	√									
Traumatic brain injury, concussion,	√	√		√	√	√		√	√			√
Vestibular neuritis	√				√	√	√	√		√		√
Vestibular paroxysmia	√	√		√	√			√		√		√
Vestibular schwannoma	√	√			√	√	√	√		√		
Neurologic												
Arnold Chiari malformation	√	√						√	√			
Ataxia	√						√	√	√			√

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	VFO	Audio	OAE	BAER	cVEMP	oVEMP	vHIT	VNG	RCT	OCT or fundus photo	ECoG	CDP
Cerebro-vascular	√						√	√		√		
Congenital nystagmus	√							√	√			√
Hydro-cephalus	√							√				√
Migraine associated vertigo	√	√	√	√	√		√	√	√			√
Movement disorders (PSP, MSA)	√			√	√	√		√	√			√
Neuropathies												√
Paraneoplastic syndrome	√							√				√

Abbreviations: **VFO** = video Frenzel oculography, **OAE** = otoacoustic emissions, **BAER** = brainstem auditory evoked responses, **cVEMP** = cervical vestibular evoked myogenic potentials, **oVEMP** = ocular vestibular evoked myogenic potentials, **vHIT** = video head impulse testing, **VNG** = videonystagmography, **RCT** = rotatory chair testing, **OCT** = optical coherence tomography, **ECoG** = electrocochleography, **CDP** = computerized dynamic posturography.