

INFORMED CONSENT FOR BALANCE AND EYE MOVEMENT TESTS
UCLA SCHOOL OF MEDICINE, DEPARTMENT OF NEUROLOGY
Adult/Parent Consent Form/Youth Assent Form (13 – 17)

In the statements below, the word "you" refers to you or to your child or ward. You are asked to participate in a research study conducted by Robert Baloh, M.D., and his associates at the University of California, Los Angeles. You have been asked to participate in this study because either you are a patient or a family member of a patient referred to Dr. Baloh or his associates, for a diagnostic work-up of abnormal balance, abnormal eye movements and/or dizziness. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate. Approximately 200 subjects are enrolled in this research per year. The duration of your participation is limited to the amount of time the tests take (usually 2 hours or less). You do not come back for more visits.

Disclosure Statement

Your health care provider may be an investigator of this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your physician.

Purpose of the Study

The purpose of this research project is to improve our understanding of how balance and visual systems interact. By developing more exact methods of measuring balance and eye movements the investigators hope to improve the diagnosis and treatment of the many diseases that affect balance and eye movements.

Procedures

If you agree to participate and sign this consent form, we will ask you to undergo the following procedures (which typically take about two hours):

1. **Medical history.** Questions about your past health.
2. **Physical examination.** Robert Baloh, M.D., or one of his associates will conduct a brief examination (not a general physical) consisting of standard neurological tests of eye movements, balance and hearing.
3. **Special balance and eye movement tests.** The following tests are administered by a physician or a trained technician under the supervision of a physician.
 - a. *Tests which stimulate eye motion by presenting a moving visual object.* A red light moves smoothly or hops randomly or white stripes move side to side past you; and/or
 - b. *Tests which stimulate eye motion by turning the head.* The examiner stands behind you and quickly turns your head a small amount to one side and then the other.
 - c. *Tests which apply a turning or swinging motion.* You are seated in a chair which is driven by a motor. The chair moves side to side in the dark or in the light while you look at the surroundings. The speed of the chair and the amount of time before it changes directions are varied. A few tests are as long as a minute; most are less than 40 seconds, some as brief as 5 seconds. No extreme speeds are used. You wear a seat belt and your head is lightly supported against a head-rest for stability; and/or
 - d. *Tests that stimulate neck muscle contraction.* A series of clicks is presented to each ear through head phones, three 30 second trials per ear.

Eye movements are recorded by electrodes pasted onto the skin near the eyes or with video goggles and neck muscle contraction by electrodes pasted on the neck. These tests have been used routinely in the community for many years.

Potential Risks and Discomforts

The balance and eye movement tests are not experimental but have been part of standard evaluation of balance for many years. The tests can occasionally produce nausea and rarely vomiting but we know of no long term effects. These procedures may involve risks that are currently unforeseeable.

Participation and Withdrawal

The investigators will answer any questions you may have before or during the testing, or any other time you call one of the investigators whose telephone numbers appear on the following page. If at any time you wish to withdraw consent and discontinue participation in the testing you will be free to do so without prejudice by signaling the test operator. Withdrawing your consent and discontinuing participation will not prejudice to your future care at UCLA.

Potential Benefits to Subjects and to Society

You as a participant should not expect to benefit personally as a result of participation in this study. The results may lead to improved diagnosis in patients with balance and eye movement disorders.

Alternatives to Participation

The alternative to participation in this study is to have the same or similar clinical diagnostic tests performed without participating in this research.

Payment for Participation

You will not be paid for your participation in this research.

Financial Obligation

Neither you nor your insurance company will be billed for your participation in this research. If you do have balance, eye, or dizziness problems, the costs of the eye movement and balance tests are covered by the study.

Emergency Care and Compensation for Injury

If you are injured as a direct result of research procedures not done primarily for your own benefit, you will receive treatment at no cost. The University of California does not normally provide any other form of compensation for injury.

Privacy and Confidentiality

The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except:

- If necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. Authorized representatives of the UCLA Office for Protection of Research Subjects and National Institutes of Health (NIH) may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

Withdrawal of Participation by Investigator

The investigator may withdraw you from participation in this research if circumstances arise which warrant doing so. If you become ill during the research, you may have to drop out, even if you would like to continue. The investigator, Dr. Robert W. Baloh, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who do develop certain conditions may not continue to participate.

New Findings

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If the study design or use of the information is changed you understand that you will be so informed and your consent re-obtained.

Identification of Investigators

Persons you may contact to answer additional questions or if there are problems or in the event of research-related injuries: Robert Baloh, M.D., Department of Neurology, Reed Research Center, Room C-246 UCLA, (310) 825-5910.

Rights of Research Subjects

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research. If you have any questions, comments, or concerns about the study or the informed consent process you may write or call the Office for Protection of Research Subjects, 11000 Kinross Ave., Ste 102, UCLA Box 951694, Los Angeles, CA 90095-1694, (310) 825-5344.

SIGNATURE OF RESEARCH SUBJECT OR LEGAL GUARDIAN

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Name of Subject

Name of Parent/Legal Guardian

Signature of Subject or Parent/Legal Guardian

Date

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject or his/her legal guardian and have answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participation.

Name of Investigator

Signature of Investigator

Date (must be the same as subject's)

Complete in duplicate. Copy 1: Subject. Copy 2: Principal Investigator