

**INFORMED CONSENT FOR BLOOD TEST
MOLECULAR GENETIC STUDIES IN GENETIC DISEASES OF EAR AND BRAIN
UCLA SCHOOL OF MEDICINE, DEPARTMENT OF NEUROLOGY
Adult/Parent Consent/Youth Assent (13-17)**

Subject's Name: _____

In the statements below the word "you" refers to you or to your child or ward.

You have been asked to participate in a research project for the detection and definition of abnormalities of the ear and brain under the direction of Robert W. Baloh, MD, Joanna C. Jen, MD, PhD., and their associates. You have been selected because of the presence of a genetic ear and/or brain disease in yourself or a member of your family. Your participation in this study is entirely voluntary. You will read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate. We anticipate enrolling approximately 200 subjects per year. The duration of your participation is limited to the interview and donation of a blood or saliva sample. These are only done once.

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

Results of this project may enable researchers to detect, understand and prevent genetic ear and brain abnormalities in the future.

Procedures

If you agree to participate and sign this consent form, we will ask you to undergo the following procedures: Participation in this study is voluntary and involves donating a sample of blood. In addition, the study involves answering questions regarding your family which may be sensitive such as information regarding possible marriages between relatives or children conceived between relatives. The interview takes less than 30 minutes. The blood samples taken may be analyzed in various ways including study of the DNA. The amount of blood taken is about 10 cc, a little less than a tablespoon.

Alternatively, you may be asked to provide a saliva sample from which we will obtain DNA. A kit will be mailed to you with instructions on the collection method. You must spit into a small plastic tube, following the written instructions, and mail the sample back as per the instructions.

Upon completion of the study, your sample will be destroyed.

Potential Risks and Discomfort

Occasionally one or more of the following potential side effects of taking blood samples may occur: pain, bruising, slight bleeding, light-headedness, fainting and (rarely) an infection. A trained technician will be drawing the blood. The treatment or procedure may involve risks that are currently unforeseeable. There are no known risks or discomforts from the saliva collection technique.

Potential Benefits to Subjects and to Society

You will not derive any direct benefit and the potential benefit to society is an increased understanding of genetic diseases which affect the ear and brain. Your condition may become worse in spite of this research project.

Participation and Withdrawal

If you decide to participate, you are free to withdraw consent and discontinue participation at any time without prejudice to your future care at UCLA. You have the right to refuse to answer any question you may not wish to answer and that any questions you have in regard to the procedure will be answered at any time by contacting the principal investigators.

Alternatives to Participation

The alternative to participation is not to participate.

Financial Obligations

There is no cost/charge to you and/or your third party carrier for participation in this research study.

Payment for Participation

There is no compensation for participation in this research 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

No information which identifies you will be released without your separate consent except as may be specifically required by law. Each blood sample contains genetic information about your parents or ancestors such as the information contained in DNA, RNA or protein. It may be helpful to study members of your family. Your relatives will not be contacted without your permission.

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.

Genetic Information in Your Sample: Possible Limits to Individual Confidentiality

Every tissue or fluid sample contains genetic information. Recent studies have found normal and disease producing genetic variations among individuals. Such variations may permit identification of individual participants. Despite this possible limitation, every precaution will be taken to maintain your confidentiality now and in the future.

We have learned from past research has shown that we will not always be possible to predict future research findings and new technologies. You should be aware that unforeseeable problems may arise from new developments. Possible problems include insurance or employment discrimination based on genetic information.

Sometimes genetic information suggesting different parentage is obtained during research. We do not plan to report such findings to participants. Within the limits imposed by technology and the law, every effort will be made to maintain the privacy of your genetic information.

Withdrawal of Participation by Investigators

Circumstances may arise which might cause the investigator to terminate your participation before the completion of the study.

New Findings

If significant new findings develop during the course of this research that may relate to the treatment of your illness or your willingness to continue your participation in this project, such information will be given to you. If the study, the design or use of the information is to be changed, you will be so informed and your consent will be re-obtained.

Information About Your Sample

General information about what this study finds will be published but no specific information about your sample will be provided. We are a research laboratory so our results are not certified by any examining board. Obtaining general information from a project may take years.

Identification of Investigators

Robert Baloh, M.D., Department of Neurology, Reed Research Center, Room 2-246, UCLA, (310) 825-5910, Joanna C. Jen, M.D., Ph.D., Department of Neurology, Reed Research Center, Room 3-232, 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 answered all of his/her questions. I believe that he/she understands the information described in the document and freely consents to participate.

Name of Investigator

Signature of Investigator

Date (must be the same as subject's)

Complete in duplicate.

Copy 1: Subject.

Copy 2: Principal Investigator