

**INFORMED CONSENT FOR BLOOD TEST
REGARDING GENETIC STUDIES OF MIGRAINE
UCLA SCHOOL OF MEDICINE, DEPARTMENT OF NEUROLOGY
Adult/Parent Consent Form/Youth (Ages 13-17) Assent Form**

Subject's Name: _____

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

INTRODUCTION: You are asked to participate in a research study conducted by Dr. Robert Baloh and Dr. Joanna Jen from the Department of Neurology and Dr. Stanley Nelson from the Department of Human Genetics. You have been asked because you are a normal volunteer or you or someone in your family suffers from migraine headaches and episodic vertigo. Vertigo and dizziness are common symptoms that affect about 25% of patients with migraine. This study is funded by the National Institutes of Health. We anticipate enrolling approximately 300 subjects per year, a total of 1500 over the 5-year grant period. Your participation is limited to the amount of time it takes to be interviewed and provide a blood or saliva sample for DNA analysis (these procedures are only done once.)

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.

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 on this study. Before entering this study or at any time during the research, you may ask for a second opinion about your health care from another doctor who is in no way associated with this project. You are under no obligation to participate in any research project offered by your physician.

PURPOSE OF THE STUDY: Results of this project may enable researchers to identify the abnormal genes which may cause migraine headaches and episodic vertigo.

PROCEDURES: Participation in this study is voluntary and involves only donating a sample of blood. In addition, you understand that 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 will be analyzed to look for genetic factors in the occurrence of migraine headaches, including study of the DNA. The amount of blood taken is about 10 cc., a little less than a tablespoon. The investigators will discard blood collected for the purposes of this research after the study has been completed.

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 DISCOMFORTS: 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 using the saliva collection technique.

ANTICIPATED BENEFIT TO SUBJECTS: You understand that you will not derive any direct benefit from participation in this study.

BENEFIT TO SOCIETY: The potential benefit to society is an increased understanding of migraine.

ALTERNATIVES TO PARTICIPATION: The alternative to participation is not to participate.

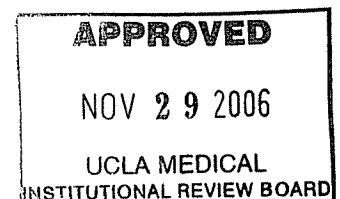
PAYMENT FOR PARTICIPATION: There is no compensation for participation in this research study.

INFORMATION ABOUT YOUR SAMPLE: This is a research project that will not benefit you directly. When the study is completed, general information about what the study found will be published.

Date of Preparation: October, 2006

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Date of Expiration: **NOV 28 2007**



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FINANCIAL OBLIGATION: There is no cost/charge to you and/or your insurance company.

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 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. Records are coded and kept by coding rather than by the individual's name. Only Drs. Baloh, Jen, and Nelson will have access to these records. You recognize that you may refuse to participate and may withdraw consent for participation at any time without prejudice and will not affect your treatment.

Each tissue and fluid sample contains genetic information about your parents and 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.

GENETIC INFORMATION IN YOUR SAMPLE: 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.

It has been learned from past research that it will not always be able 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. The investigators 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.

PARTICIPATION AND WITHDRAWAL: Your participation in this research is **voluntary**. If you choose not to participate, that will not affect your relationship with UCLA, (or UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA.

WITHDRAWAL OF PARTICIPATION BY INVESTIGATOR: The investigator may withdraw you from participating 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 will make the decision and let you know if it is not possible for you to continue.

NEW FINDINGS: During the course of the study, you will be informed of any significant 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 new information is provided to you, your consent to continue participating in the study will be re-obtained.

IDENTIFICATION OF INVESTIGATORS: In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below: Robert Baloh, M.D., Department of Neurology, Reed Research Center, Room 2-246, UCLA, (310) 825-5910. The Co-Investigators are Joanna C. Jen, M.D., Ph.D., Reed Research Center, Room 3-232, UCLA, (310) 825-5731 and Stanley F. Nelson, M.D., Department of Human Genetics, 5506B Gonda Center, UCLA, (310)794-7981.

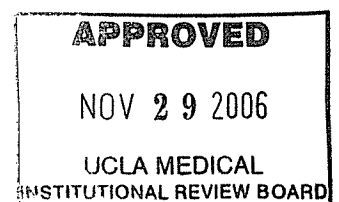
RIGHTS OF RESEARCH SUBJECTS: You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have any questions regarding your rights as a research subject, you may contact the Office for Protection of Research Subjects, 2107 Ueberroth Building, UCLA, Box 951694, Los Angeles, CA 90095-1694, telephone (310) 825-8714.

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SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

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

Signature of Subject

Date

Name of Parent/Legally Authorized Representative

Signature of Parent/Legally Authorized Representative

Date

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject or his/her legal representative, 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

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APPROVED

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