
CONSENT TO PARTICIPATE IN RESEARCH
Adult or Parent, for Minor Child

NAME OF STUDY: Molecular Genetic Characterization of Alström Syndrome

PRINCIPAL INVESTIGATORS: Jürgen K. Naggert, Ph.D.

Study Sponsored By: NIH Grant HD036878

Date of IRB Approval:

Name of participant: _____ Age: _____

Name of parent or guardian, if applicable: _____

INTRODUCTION

We invite you to take part in a research study at The Jackson Laboratory.

First, we want you to know that:

Taking part in a Jackson Laboratory research study is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled.

You may receive no direct therapeutic benefit from taking part. The research may give us knowledge that may help you and other people in the future.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with the study coordinator at The Jackson Laboratory, or with family, friends or your personal physician or other health professional.

NOT VALID WITHOUT THE IRB STAMP
OF CERTIFICATION

APPROVED BY

**THE JACKSON LABORATORY
INSTITUTIONAL REVIEW BOARD**

December 8, 2009

Do not sign after December 7, 2010

DETAILS OF THE STUDY

1. Purpose of the study: The purpose of this study is to determine the molecular basis of Alström Syndrome, a genetic disorder characterized by progressive retinal degeneration and hearing impairment, obesity and type 2 diabetes, and other metabolic alterations, and to understand how the gene that causes Alström Syndrome, ALMS1, functions in the human body.

2. Procedures to be followed and approximate duration of the study: We will withdraw of up to 50 cc (about 6 tablespoon) of blood using sterile, disposable equipment and ask you to complete a medical interview.

The blood to be withdrawn will be used only for Alström Syndrome research. DNA will be extracted from the blood samples of each participant and will be used in Dr. Naggert's research laboratory for genetic studies, with the eventual goal of identifying and understanding the mutations within the gene that causes Alström Syndrome.

Your identity will remain confidential. Samples within the laboratory are identified both by a number and/or a four-letter code identifier. The key to the codes is kept in a computer that is accessible only by password to researchers involved in this project. Medical records are kept in a locked filing cabinet and will not be made available to third parties without your written consent.

A portion of the blood that we withdraw will be stored for possible analysis in the future. DNA and blood samples will be stored indefinitely and will not be available to third parties, unless the participant authorizes the transfer in writing.

If clinical tests, assessed by a certified diagnostic laboratory, are carried out on your blood sample, results from these laboratory tests will be provided to you and/or your personal physician at your request. However, information about the genetic testing for Alström Syndrome may take an indeterminate length of time and may not be available to you. Any genetic results obtained as a part of this research should be confirmed by a licensed genetic testing laboratory.

The medical interview and questionnaire will include questions about your family ancestry and personal health history. Collaborating investigators may also review data derived from your questionnaire and interview.

We may request your permission to contact your personal physicians for further information pertaining to your medical condition.

3. Expected costs to participant: There are no costs to you or your physicians for your participation in this study.

4. Description of discomforts, inconveniences and/or risks: There may be the minor discomfort of venipuncture, and the minimal risk encountered in a normal blood donation program. Although the majority of people experience no difficulty when donating blood, a few feel faint or weak during or following the blood donation.

5. Anticipated benefits from this study: The potential benefit of this study may be advancement of knowledge of Alström Syndrome and related diseases. The results of the study will not be immediate and you or your family may not benefit directly from participation in the study.

OTHER PERTINENT INFORMATION

1. Confidentiality: When results of a research study at The Jackson Laboratory are reported in medical journals or at scientific meetings, the people who take part are not named or identified. The Jackson Laboratory and collaborators related to this study will not release any information

Informed Consent Document (continuation)

about your research involvement without your written permission.

The Federal Privacy Act protects the confidentiality of your medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

2. Policy Regarding Research-Related Injuries: If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You should report any injury to Dr. Jürgen K. Naggert at (207) 288-6382, or Jan D. Marshall at (207) 288-6385 (800-371-3628) and to the Institutional Review Board for Human Subjects Research at (207) 288-6772.

3. Compensation for Participation: You will not receive any monetary or other form of compensation for your participation.

4. Problems or Questions: If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator Dr. Jürgen K. Naggert (207) 288-6382. Other researchers you may call are: Jan D. Marshall, Genetics Coordinator, at [207] 288-6385.

For additional information about giving consent or your rights as a participant in this study, please feel free to contact The Jackson Laboratory Institutional Review Board at 207-288-6772.

5. Data and Samples Collected During Study: The Jackson Laboratory is dedicated to improving public health through finding the causes and cures of disease. The data and samples collected during this study are important to this study and to future research. Sometimes such research may result in findings or inventions that have value if they are made or sold. If this material helps lead to the creation of a product or idea, whoever creates that product or idea will own it. You will not receive any financial benefit from the creation, development, use or sale of that product or idea.

6. Consent Document: You will be provided with a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:			
A. Adult Consent		B. Parent's Permission for Minor	
I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.		I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.	
_____	_____	_____	_____
Signature of adult patient/volunteer or legal representative	Date	Signature of Parent(s)/Guardian	Date

Informed Consent Document (continuation)

C. Child's Verbal Assent (if applicable)

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions.
I hereby consent to take part in this study

Signature of Parent(s)/Guardian

Date

Statement of Investigator/Designee Obtaining Informed Consent

I certify that I have discussed the research project with the participant, and have explained all of the information contained in the consent form including any adverse reactions that may reasonably be expected to occur. I further certify that all those participating in the discussion were encouraged to ask questions and that all questions have been answered.

Signature

Printed name and title