

University at Buffalo
Consent to Participate in a Research Study - Statin Participants

GENETIC SUSCEPTIBILITY TO LIPID-LOWERING DRUG-INDUCED MYOPATHIES

It is a principle of medical ethics that the human subject participants of a research protocol should be informed of the purpose and benefits of the project; the research methods to be used; the potential risks or hazards of participation and the right to ask for further information at any time during the research procedure. You have the right to know whether medical treatment or compensation is available for physical injuries incurred as a result of participation in the project. Your choice to participate is a voluntary one, and you are free to withdraw from the research project at any time. Your signature at the end of this consent form will indicate that the principal investigator, or his/her agent, has answered all your questions and that you voluntarily consent to participate in this investigation.

Who will be conducting the study?

Principal Investigator:
Georgirene D. Vladutiu, Ph.D., Professor of Pediatrics, Neurology and Pathology,
University at Buffalo School of Medicine & Biomedical Sciences

Who is sponsoring the research study?

National Institutes of Health

Where will the study be conducted?

Laboratory testing will be performed in the Robert Guthrie Biochemical Genetics Laboratory at Buffalo General Hospital, 100 High Street, A762, Buffalo, NY 14203. The collection of specimens for analysis will be performed at designated blood draw stations associated with Kaleida Health for local participants and at convenient blood draw stations designated by referring physicians for out of town participants.

What is the purpose of the research?

The purpose of the research is to (1) determine if you are either affected with or are susceptible to developing a metabolic muscle disease. [Metabolic muscle diseases are disorders that impair your ability to use your muscles effectively and usually cause pain or weakness]; and (2) collect and analyze clinical and laboratory data from you and other participants to determine the underlying cause(s) of muscle disease that occur in certain individuals who take cholesterol-lowering drugs such as, but not limited to, Lipitor and Zocor.

Who is being asked to participate in this research study?

You are being asked to participate because (1) you have experienced muscle symptoms such as pain, weakness, or exercise intolerance while taking cholesterol-lowering medication, or (2) you are an

Subject initials: _____
Version 9/20/09

1

For IRB Use	UNIVERSITY AT BUFFALO HEALTH SCIENCES IRB APPROVAL FROM <u>10/20/2009</u> TO <u>10/19/2010</u>
-------------	------------------------------------------------------------------------------------------------------

individual without any muscle pain or weakness who has just begun taking cholesterol-lowering medication or have been taking the medication for a variable length of time.

What procedures will be performed for research purposes?

If you decide to participate in this research study, you will undergo the following procedures free of charge that are not part of your standard medical care: (1) A small amount of blood (about 1 teaspoon) will be taken from your arm in order to test for inherited indicators of muscle disease. Inherited indicators will include possible mutations (genetic material; genes) or variations in a certain chemical in the blood known as creatine kinase that is an indicator of any muscle damage. (2) You will be asked to fill out a brief questionnaire about your medical history and how you feel physically at the time you begin participation in the study. (3) You will be asked to fill out a follow-up questionnaire again at 6 months from the time you entered the study. You will be asked to report a change in your health with respect to muscle pain or weakness sooner than time at which you fill out the 6 month questionnaire if you believe there to be a significant change in your health status.

What are the possible risks, side effects, and discomforts of this research study?

The only risk to blood draw is a slight risk of bruising on your arm at the site of the blood draw. This should disappear within a few days. There should be no other risks or side effects from participation in this study.

What are the possible benefits from taking part in this research study?

The benefits of this study to you are that we will determine your risk for having selected hereditary muscle diseases and other contributing genetic variation that may increase your risk for side effects from cholesterol-lowering drugs. If we find that you are at risk for one of the disorders we will be studying, then this information can be used by your physician to reduce your risk for having serious side effects from cholesterol-lowering drugs. This testing will provide more complete monitoring of how you respond to cholesterol-lowering drugs than is provided to the average patient not participating in the study.

Will I be told of any new information or new risks that may be found during the course of this study?

In the unlikely event that we find an abnormal risk factor or any significant new developments that may be important to your health care, you will be notified. Our findings will not be provided to your doctor or anyone else without your written permission.

Will my insurance provider or I be charged for any costs of any procedures performed as part of this research study?

There are no costs to you associated with this study.

Who will pay if I am injured as a result of taking part in this research study?

Routinely, the Kaleida Health System, Erie County Medical Center, the Catholic Health System and/or the University at Buffalo, State University of New York, its agents, or its employees do not compensate

For IRB Use	UNIVERSITY AT BUFFALO HEALTH SCIENCES IRB APPROVAL
	FROM <u>10/20/2009</u> TO <u>10/19/2010</u>

for or provide free medical care for human subjects/participants in the event that any injury results from participation in a human research project. In the unlikely event that you become ill or injured as a direct result of participating in this study, you may receive medical care, but it will not be free of charge even if the injury is a direct result of your participation.

Will I be paid for participating in this study?

While there will be no financial compensation for your participation in this study, you will have the opportunity to obtain information potentially important to your healthcare that is not routinely available as part of your standard medical care.

Who will know about my participation in this research study?

Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. In order to monitor this research study, representatives from the Health Sciences Institutional Review Board, and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records that may reveal your identity.

Blood will be used only for science. No names will ever be used and data will be kept confidential. A small portion of the blood samples will be stored for future testing. The nature of this testing is not known at this time; however, investigators may look at inherited factors which are related to diseases by examining DNA obtained from the stored samples. This DNA may be used for future analysis of genes that may influence disease.

By signing this form, you are giving consent for any future studies of genes that we may perform in the laboratory.

The blood sample will remain the property of The Robert Guthrie Biochemical Genetics Laboratory, and may be shared with other researchers as long as confidentiality is maintained. All names will be removed from samples prior to being given to other researchers. The blood samples and the DNA obtained from the blood are stored and tested with an identifying number, and your name will not appear on the stored samples. You will not be told of these possible tests, nor will you receive results of any of these tests.

By signing this form, you understand that there is a possibility that the blood that you are providing under this study may also be used in other research studies that could potentially have commercial applicability. You will be unable to participate in receiving any revenues generated by commercial application. Results of studies may be reported in medical journals or at meetings. However, individuals in the study will not be identified in any way.

Is my participation in this research study voluntary?

Your participation in this study is voluntary and you may stop your participation at any time without prejudice and without affecting future health care by writing your request to withdraw to the Principal Investigator Dr. Georgirene Vladutiu.

Subject initials: _____
Version 9/20/09

For IRB Use	UNIVERSITY AT BUFFALO HEALTH SCIENCES IRB APPROVAL
	FROM <u>10/20/2009</u> TO <u>10/19/2010</u>

PERTAINING TO CLINICAL DIAGNOSTIC STUDIES PERFORMED IN OUR LABORATORY

(1) The Use of Clinical Diagnostic Laboratory Results

Laboratory results generated from diagnostic studies of your muscle biopsy, blood specimens in our diagnostic laboratory will be added to the research data generated by your participation in our study. The addition of these findings will provide the most complete understanding of the cause of your symptoms. If you do not wish to have laboratory results from your diagnostic studies included in our research study, please initial the declination below.

(a) I decline to permit the use of clinical diagnostic laboratory results from my muscle biopsy, blood for this research study. Initials _____

(2) The Use of Residual (leftover) specimens for additional biochemical or molecular studies.

Residual specimens (muscle, blood) that remain after clinical diagnostic testing is completed in our laboratory will be used for any additional studies (biochemical or molecular) that will contribute to our understanding of statin myopathy. If you do not wish to have residual specimens from your diagnostic studies included in our research study, please initial the declination below.

(a) I decline to permit the use of specimens leftover from clinical diagnostic studies to be used for this research study. Initials _____

For IRB Use
UNIVERSITY AT BUFFALO
HEALTH SCIENCES IRB APPROVAL
FROM 10/20/2009 TO 10/19/2010

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I am encouraged to ask questions about any aspects of this research study before signing this document. If, in the future, I have questions, concerns, or complaints about the research, I should contact:

Georgirene D. Vladutiu, Ph.D. 716-859-7741

If I have any questions, concerns, or complaints about my rights as a research participant or want to speak to someone who is not associated with the research, I should contact the staff at the Office of the Health Sciences Institutional Review Board, University at Buffalo: (716) 829-2752.

By signing this form I do not waive any of my legal rights.
By signing this form, I voluntarily agree to participate in this research study.

(Print) Name of **Participant**

Signature of Participant

Date

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A signed copy of this consent will be given to the participant.

(Print) Name of **Person Obtaining Consent**
(PI or Designee)

Signature of Person Obtaining Consent

Date

