Date: _____

Participant ID #_____
(office use only)

MOUNT SINAI HOSPITAL
Rebecca Macdonald Centre for
Arthritis & Autoimmune Disease

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CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY:
Patients with Vasculitis

Study Title: Identification of the Genes and Proteins Responsible for Vasculitis

Principal Investigator: Dr. Katherine Siminovitch
Professor, University of Toronto

Co-Investigator: Dr. Christian Pagnoux
Division of Rheumatology

Study Sponsor: Ontario Research Fund

Introduction

Before agreeing to participate in this research study, it is important that you read and understand this consent form. This form provides all the information we think you will need to know in order to decide whether you wish to participate in the study. If you have any questions after you read through this form, ask your doctor or study personnel. You should not sign this form until you understand everything on this form. You may also wish to discuss your participation in this study with your family doctor, a family member, or close friend. Participation in this study is voluntary.

Purpose of the Research

To identify and characterize the genes and proteins which cause and/or modulate genes and proteins responsible for vasculitis. The causes of vasculitis (Giant Cell

Arteritis, Takayasu's Arteritis, Polyarteritis Nodosa, Granulomatosis with Polyangiitis, Microscopic Polyangiitis, or Eosinophilic granulomatosis with polyangiitis) are unknown. It is likely that a number of different factors are involved. There is evidence that one factor which puts people at risk of developing vasculitis may be inherited (a gene). This particular gene has not been identified. Additionally, we want to characterize the proteins that are involved in vasculitis, to make the study well-rounded - including both gene and protein markers of disease. It is hoped that this study may help determine the genetic and protein factors associated with this disease.

Description of Research

In follow up to a letter from your physician or your response to the study advertisement, the Study Coordinator will explain the study to you. If you choose to participate, you will be asked by the coordinator to sign a form indicating informed consent.

You will also be asked to discuss this study with your family members to determine whether they would also like to participate in the study. Their participation will be limited to providing a saliva sample, signing a consent form and completing a questionnaire.

Upon signing this informed consent, you allow your physician to release only those documents pertaining to your disease that are required by this study. As well, you agree to give up all right to ownership on materials obtained for purposes of this genetics research project.

You will complete a questionnaire that provides the researchers with a brief history of your disease and names of your relatives. You will be asked for permission by the study coordinator to contact affected relatives you have named to discuss this study and ask if they are interested in participating.

You will have the option of providing either 1.) Four (4) tubes of blood (approximately 34 ml) at one visit, 2.) Two saliva samples or 3.) Both 1. and 2. The reason we also ask for both blood and saliva samples in option 3) is because it provides the research scientists with more genetic material on which do to thorough analyses.

The information gained from this study will not be available to you in the form of a test result. As this type of research often takes a number of years to complete, the information will have no direct impact on your current medical care.

The blood samples obtained will be processed to isolate for DNA,and proteins. These samples will be stored for an indefinite period for use in ongoing studies of the genes responsible for vasculitis. The results of these tests will not be released to a third party unless consent is given by you.

Potential Harms (Injury, Discomfort, Inconvenience)

At the time of the blood sample collection, there may be some temporary pain or bruising. Otherwise, there are no known harms associated with participation in this study.

Potential Benefits

You will not benefit directly or financially from participating in this study.

Participation Expenses

Should you incur any expenses for traveling to and from the hospital, or parking at the hospital, you will be reimbursed up to $45.00.

Destruction of Samples

The study doctor will keep records linking your identity with your blood sample for the period of 25 years. Your blood sample and material obtained from your blood sample will be destroyed when the testing described above is complete.

Development for Commercial Gain

I understand that research carried out on my sample by researchers at Mount Sinai Hospital or their collaborators may lead to the development of marketable treatments, devices, new drugs or patentable procedures. However, I understand that I will not benefit from commercial procedures that will remain with Mount Sinai Hospital and their research partners.

Confidentiality and Privacy

Records of data collected during this research relating to you and your care will be kept confidential. No information that discloses your identity will be released or published without your consent. No information regarding the results of this research will become

part of your health record. The genetic material isolated as a result of this research will be stored with identifying information so that, as new genes are discovered which are implicated in vasculitis, it is possible for research in this area to continue. These samples will remain the property of the investigators.

Please note that if you do choose to provide your email address below (optional) for study correspondence, this form of communication may not be secure and there are other alternative options of communicating with study coordinator, such as via telephone, if you so prefer.

Publications of Results

We will undertake to alert the participants in the event of any publication of results. Such publications, however, will not identify you as a study participant. This research data may be presented at conferences, seminars or other public forums, but no identifiers will be included so as to ensure participant confidentiality.

Compensation for Injury

If you become ill or are physically injured as a result of participation in this study, medical treatment will be provided. The reasonable costs of such treatment beyond that provided by your insurance will be covered by the sponsor, Ontario Research Fund, for any injury or illness that is directly a result of participation in this trial. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities**.**

Participation and Withdrawal

Participation in research is voluntary. If you choose not to participate, you will continue to have access to customary care. If you choose to participate in this study, you can withdraw at any time without any effect on the care you will receive. Withdrawal from the study does not include withdrawal of any data compiled up to that point.

Contact Information

If you have any questions about the study, please call the Study Coordinator at (416) 586-4800 x5492. If you have any questions about your rights as a research subject,

please call Dr. R. Heslegrave, Chair of the Mount Sinai Hospital Research Ethics Board at (416) 586-4875. This person is not involved with the research project in any way and calling him will not affect your participation in the study.

If you seek emergency care or if hospitalization is required, please alert the treating doctor that you are enrolled in a research study being conducted by the study doctor.

IDENTIFICATION OF THE GENES AND PROTEINS RESPONSIBLE FOR VASCULITIS

Consent:

I acknowledge that the research study described above has been explained to me and that any questions I have asked have been answered to my satisfaction. I have been informed of the alternatives to participation in this study, including the right not to participate and the right to withdraw without compromising the quality of medical care. As well, the potential risks, harms, and discomforts have been explained to me and I also understand the benefits (if any) of participating in the research study.

I understand that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions from their legal and professional duties. I know that I may ask now, or in the future, any questions I have about the study or the research procedures. I have been assured that records relating to my care and me will be kept confidential and that no information will be released or printed that would disclose personal identity without my permission unless required by law. I have been given sufficient time to read and understand the above information.

I also agree to inform the Study Coordinator of this project (*Identification of the Genes and Proteins Responsible for Vasculitis)* of any change in my address or phone number.

Please indicate (with a check mark) what samples you agree/consent to donate for this study:

□ Blood samples (4 tubes-approx 34 mL)
□ 2 Saliva samples
□ Blood samples (4 tubes-approx 34 mL) and 2 Saliva samples

SIGNATURE (Participant)	Date
Name (In capital letters)	Date of Birth (DD/MM/YYYY)
Address (Street)	Telephone Number
City, Province/State, Country	Postal/Zip Code

_____
Email Address *(optional)*

_____ _____
SIGNATURE (Witness) Date

Consent is continued on the next page.

IDENTIFICATION OF THE GENES AND PROTEINS RESPONSIBLE FOR VASCULITIS

Patient Participation Authorization to Provide and Disclose Professional Information

The undersigned hereby authorizes _____ to
(Please print the name of your Rheumatologist)
disclose, reveal, open for observation or inspection, or provide copies of any report, statement, analysis, diagnosis, or any other medical or professional record _____ to:
(Please print your name)

Dr. Katherine Siminovitch
Mount Sinai Hospital
600 University Avenue, Room 778D
Toronto, Ontario M5G 1X5

Physician's Contact Information:

Physician's Name: _____

Address (Street): _____

City/Province/State/: _____
Country
Postal/Zip Code: _____

Telephone Number: _____

Fax Number: _____

SIGNATURE (Participant):_____

SIGNATURE (Witness): _____

Date: _____