

Immunity and Infection Research Centre



SUBJECT BLOOD DONOR CONSENT FORM

Title of Study: Elucidation of the mechanisms by which the human immune system responds to infection or organ transplantation

Principal Investigator: Megan K. Levings, PhD
Assistant Professor
Dept. of Surgery, University of British Columbia &
Immunity and Infection Research Centre
Vancouver Coastal Health Research Institute
tel: 604-875-4111 ext 66742

Sponsors: Michael Smith Foundation for Health Research
Canadian Institutes for Health Research
VGH & UBC Hospital Foundations
Multiple Sclerosis Society of Canada

Emergency Telephone Number: 604-875-4111 extension 66742

You are being invited to take part in this research study because you are in good health, not pregnant, and have never been diagnosed with hepatitis B or C, HIV infection, or any other transmissible infectious disease.

Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand why the research is being done and what it will involve. If you wish to participate, you will be asked to sign this form. You do not have to provide any reason should you decide not to participate. Should you refuse to participate or withdraw, it would not in any way jeopardize your future medical care at this institution

This study is being conducted by researchers at the Infection and Immunity Research Centre at the Vancouver Coastal Health Research Institute and the University of British Columbia. In addition to Dr. Levings, other Co-Investigators on this project include: Dr. Barrett Benny, Dr. Raewyn Broady, Dr. W. Robert McMaster, Dr. Neil Reiner, Dr. Urs Steinbrecher, Dr. Jonathan Choy, Dr. Robert Brunham, Dr. Yossi Av-Gay, Dr. Vincent Duronio, Dr. Zakaria Hmama, and Dr. Ted Steiner. The study is sponsored by the Michael Smith Foundation for Health Research, the Canadian Institutes for Health Research, the VGH & UBC Hospital Foundations and the Multiple Sclerosis Society of Canada.

The purpose of this study is to develop new ways to improve treatments for a variety of infectious diseases and improve the success of organ transplantation. White blood cells are a key component of our immune system, and we are investigating the changes that these cells undergo when they encounter foreign agents such as bacteria, viruses or transplanted organs. The overall goal is to integrate discoveries made by individual investigators at the Immunity and Infection Research Centre and identify common pathways in the immune response to infections in order to develop new therapies to combat infectious diseases and improve the success of organ transplantation.

This study requires blood from healthy subjects, and could not be performed with any alternate source of biological material.

If you agree to take part in this study, the procedures you can expect will include the following:

- A brief physical exam to measure blood pressure and a finger prick to test for anemia
- Blood withdrawal from a vein in your arm through a sterile needle by a trained member of the Cell Separator Unit nursing staff at VGH. You may experience momentary discomfort associated with insertion of the needle, and a small bruise occasionally occurs at the puncture site.
- One unit of blood will be collected (1 3/4 cups, an amount equal to a standard donation at Canadian Blood Services)
- Although the amount of blood to be removed will not exceed 10% of your total blood volume, you may experience lightheadedness or dizziness. This is usually a reaction to discomfort from the needle. If this occurs during the blood withdrawal, the procedure will be stopped. The dizziness subsides after a few minutes of rest.

The procedure will take approximately 20 minutes, and you will be asked to stay seated for an additional 10-15 minutes to ensure you have recovered from any lightheadedness or dizziness. The blood that was removed will be regenerated by the bone marrow within 2 weeks, and there are no long-term side effects associated with the procedure. The maximum amount of blood that can be donated is 1 unit (450 ml) every two months.

The cells from your blood may be used immediately, or frozen for use at a later date. However, regardless of whether they are used immediately or stored in liquid nitrogen, your cells will be used strictly for research in the current study. No other investigators will have access to the material, and it will not be stored as part of the inventory of a blood bank.

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator, or his or her designate, Health Canada, and by the UBC Research Ethics

Board for the purpose of monitoring the research. Your identity will be recorded in a confidential logbook; however, no records which identify you by name or initials will be allowed to leave the Investigators' office. However, you should be aware that your blood may be tested for the presence of infection with Hepatitis C and/or HIV-1 and -2. Pre-testing counseling will be made available upon request. Should any one of these tests give a positive result, we are obligated by law to report these results to the BC Centre for Disease Control, and they will become part of your permanent health record. Post-positive-test counseling services will be made available to you and your family.

The investigators and/or their partners/immediate family members will not receive any personal benefits connected to this research study.

You should understand that Canadian legislation prohibits the sale of human tissues, including blood. You will however receive light refreshments following donation and free parking at Vancouver General Hospital.

If you have any questions or desire further information about this study before, during or after participation, you can contact Dr. Megan Levings anytime, 7 days a week, at 604-875-4111 extension 66742. You may also contact Dr. Levings should you wish to be informed of the progress in this project, and/or of how the data collected from the blood you donate has contributed to improving the success of treating infectious diseases and the outcome of organ transplantation.

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, you may contact the Research Subject Information Line in the University of British Columbia Office of Research Services at 604-822-8598.

Immunity and Infection Research Centre



UNIVERSITY OF
BRITISH
COLUMBIA



CONSENT TO PARTICIPATE AS A SUBJECT BLOOD DONOR

- I have read and understood all 4 pages of this consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without jeopardizing my future medical care at this institution.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I have read this form and I freely consent to participate in this study.
- I have been told that I will receive a dated and signed copy of this form.

Printed name of subject

Signature

Date

Printed name of witness

Signature

Date

Printed name of principal investigator
or designated representative

Signature

Date
