BC Children's Hospital
An agency of the Provincial Health Services Authority

Childhood Diseases Research Theme
BC Children's Hospital Research Institute
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Participant Information and Consent Form

Title of Study: Immune Regulation in Autoimmunity and Transplantation (BCCHR Phlebotomy Protocol)

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Sponsors:
Canadian Institutes for Health Research
Genome Canada & Genome BC
BioCanRx National Centre of Excellence
The Kenneth Rainin Foundation
Crohn's & Colitis Canada
The Juvenile Diabetes Research Foundation
The Canadian Cancer Society Research Institute
Marie Curie Actions
Leona M. and Harry B. Charitable Helmsley Trust
Michael Smith Foundation for Health Research
The National Institutes for Health

Non-Emergency Telephone Number: 604-875-2000 extension 4686

1. Invitation

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.

2. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

3. Who is conducting this study?

This study is being conducted by researchers at the BC Children's Hospital Research Institute and the University of British Columbia. In addition to Dr. Levings, other co-Investigators on this project include: Dr. T Kieffer, Dr. T. Steiner & Dr. B Verchere. The study is sponsored by Canadian Institutes for Health Research, Genome Canada, Genome BC, Crohn's & Colitis Canada, BioCanRx National Centre of Excellence, The Juvenile Diabetes Research Foundation, The Kenneth Rainin Foundation, Marie Curie Actions, The Canadian Cancer Society Research Institute, Leona M. and Harry B. Charitable Helmsley Trust, the Michael Smith Foundation for Health Research and the National Institutes for Health.

4. Background

The immune system is designed to eliminate danger (such as viruses and bacteria), but sometimes it also attacks normal cells in the body, or tissues which have been transplanted into the body. If this happens then autoimmune diseases (e.g. type 1 diabetes, rheumatoid arthritis) or transplant rejection can occur. We are interested in understanding why these unwanted immune responses sometime happen and how they can be prevented or reversed. Much of our research is focused on a special type of white blood cell called a regulatory T cell (or Tregs for short) which naturally control immune responses. We aim to better understand the role of these cells, how they interact with other immune cells, and to harness their immunoregulatory properties for clinical applications. Part of this research also involves harmonizing research procedures between different labs across Canada and the US so as to be better able to compare and integrate data.

5. What is the purpose of the study?

The purpose of this protocol is to collect blood from healthy adults so that we can study how different types of white blood cells work together to regulate immune responses. We also use blood samples to develop and standardize assays which can then be used to analyse samples from patients with immune-based disorders in other studies. Some examples of how this research can impact health include the following: 1) identification of new ways to prevent and treat type 1 diabetes; 2) understanding what causes inflammatory bowel diseases and how best to treat them; and 3) using T regulatory cells to directly treat transplant rejection and autoimmune disease treatment by injecting them into the patient (cell therapy).

6. Who can participate in this study?

You may be able to participate in this study if you are*:*

- In good health
- Over 18 years of age
- Not diagnosed with Hepatitis B or C, HIV infection, or other blood-transmissible infectious diseases
- Not pregnant

7. Who should not participate in this study?

You will not be eligible to participate in this study if you do not meet the eligibility criteria listed above

8. What does the study involve?

If you have expressed interest in this study, you will be given this consent form to review. You will have as much time as you require to read the form and decide if you wish to participate. This study requires blood from healthy participants, and could not be performed with any alternate source of biological material. If you agree to take part in this study, the procedures and visits you can expect will include the following:

- Blood withdrawal from a vein in your arm through a sterile needle by a trained member of the C&W Laboratory Services staff at one of the two blood collection laboratories at C&W. You may be required to wait up to 20 min for this. If you prefer, a member of our research staff who is a medical doctor (and certified to practice in Canada by an appropriate Medical Association) will take the blood right away in a designated area of the BCCHR Clinical Support Building. You may experience momentary discomfort associated with insertion of the needle, and a small bruise occasionally occurs at the puncture site.
- Between 10-60 ml (approximately 1-4 Tbsp) of blood will be collected
- The procedure will take approximately 5 minutes. The amount of blood removed is minimal and no after-effects are expected.

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 frozen, your cells will be used strictly for research in the current study. In some cases we may want to send samples of your blood cells to other collaborating labs within Canada or the US; these labs will have ethics approval to partake in this study. There will be an option to indicate if you allow us to share your sample and non-personal information on the last sheet of this consent. No information which can identify you will be sent to these other labs and your samples will not be stored as part of the inventory of a blood bank. These studies may also involve collaborations with companies to test new reagents or equipment that could help us to answer our research questions.

You should be aware that these studies may also involve genetic manipulation; small sections of genetic material in your T cells may be sequenced and new genetic material inserted to give the T cells a certain capability (for example: the ability to target certain tissues such as a transplanted organ or a harmful immune cell). Some work may also involve humanized mice,

these are mice which carry specific human immune genes that allow us to test the interaction with other human immune cells.

9. What are the possible harms and discomforts?

You may experience light-headedness 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.

10. What are the potential benefits of participating?

There will not be direct benefits to you from taking part in this study. We hope that the information learned from this study can be used in the future to benefit other people with a variety of diseases caused by the immune system.

11. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information and/or samples collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data and/or samples will not be able to be withdrawn for example where the data and/or sample is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data and/or samples, please let the investigators know.

12. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or her designate by representatives of the University of British Columbia for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the Investigator.

Any study related data and samples sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries, (e.g. the Patriot Act in the United States) dealing with protection of information may not be as strict as in Canada. However, all study related data and samples that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of samples derived from your blood to other Canadian or US universities for publically funded, ethics-approved projects.

13. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the study investigators, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

14. What will the study cost me?

All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you.

15. Who do I contact if I have questions about the study during my participation?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact Dr. Megan Levings during working hours at 604-875-2000 extension 4686.

16. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please reference the study number (H18-02553) when contacting the Complaint Line so the staff can better assist you.

17. After the study is finished

Results from these studies will be reported in peer-reviewed publications and at scientific conferences. The de-identified samples may be kept for up to 10 years.

Participant Consent: Immune Regulation in Autoimmunity and Transplantation

STUDY ID _____

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able 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 results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.

Please check one of each of the two options below:

Transfer of Blood Samples:

☐ YES, I allow my de-identified samples to be shared with study collaborators in Canadian or US universities

OR

☐ NO, I do not want samples of my blood to be shared with collaborators outside of this research institute.

Re-contacting for future consent:

☐ YES, I would be willing to be contacted to participate in future studies **OR**

☐ NO, please do not contact me to ask about participation in future studies.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

_____	_____	_____
Participant's Signature	Printed name	Date

_____	_____	_____	_____
Signature of Person Obtaining Consent	Printed name	Study Role	Date