Name _____
BCCA # _____

BC Cancer Agency
CARE & RESEARCH

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Participant Information and Consent Form
Biology of Lymphoid Cancer

TITLE OF RESEARCH PROJECT: Biology of Lymphoid Cancer
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Sponsors and Associated Projects:

British Columbia Cancer Foundation
British Columbia Cancer Agency Centre for Lymphoid Cancer
Terry Fox Foundation and Research Institute
Canadian Cancer Society Research Institute
Genome British Columbia
Genome Canada
National Cancer Institute (United States)
The Cancer Genome Atlas (TCGA)
SPECS II – Molecular Diagnosis and Prognosis in Aggressive Lymphoma
Canadian Institutes of Health Research
Canadian Institutes of Health Research Centre for epigenomic mapping techniques
NanoString Technologies, Inc

Background

Non-Hodgkin lymphoma, Hodgkin lymphoma, myeloma and lymphocytic leukemia are called lymphoid cancers because they originate in white blood cells called lymphocytes. Altogether these cancers are the fourth most common cancer type seen in Canada and their frequency is rising each year. Research to determine how these cancers begin, what causes them, how to treat them and the long term effects of

treatments is urgently needed. The researchers at the Centre for Lymphoid Cancer at the BC Cancer Agency are conducting such research. With this consent form these researchers are inviting you to help with this research.

You have been referred to a cancer specialist either because you have one of the lymphoid cancers or because the advice of a specialist who knows about the lymphoid cancers might be helpful in your medical care. Whether or not you have a cancer your participation in our research could provide very useful information. Participation is entirely voluntary. You may choose to participate or not and you may decide to withdraw your participation at any time without affecting your medical care. Please read this form carefully and ask any questions you may have. This research is being conducted with financial support from many sources including the sponsors named above on this page; private donors; unrestricted grants from pharmaceutical companies; and other sources. The information from this research, however, remains entirely under the control of the researchers in the Centre for Lymphoid Cancer.

Why are you being asked to participate in this research?

You are being asked to participate in this research either because you have one of the lymphoid cancers or because the advice of a specialist who knows about the lymphoid cancers might be helpful in your medical care.

What will happen if you participate in this research?

If you participate in this research you give the researchers at the Centre for Lymphoid Cancer permission to

1. Use for research the material from any of your biopsies that is left over after all the tests necessary to establish a diagnosis;
2. Have access to the information in your medical records, wherever they are kept, to keep track of what happens to you medically in the future;
3. Collect a sample of blood from you (up to 30 mL, 2 tablespoonsful)
4. Collect additional samples of blood (up to 2 tablespoonsful) if needed because the first sample has been used up or a more recent sample is needed.
5. Contact you in the future to offer the chance to participate in other research about lymphoid cancers. You remain entirely free to choose whether or not to participate in this future research if you are contacted.
6. Share the information learned from analyzing your biopsies and blood sample with other researchers around the world conducting cancer research. This may include analysis of the genetic code in your cancer cells and your normal cells. Any such genetic code analysis will only be shared with other researchers who have pledged to keep the information confidential, using secure methods of information exchange that preserve confidentiality. The shared information itself will **not** include any information that identifies you. Access to this protected information will be allowed for projects using the information for research relevant to the biology, causes, treatment and late complications of treatment of cancer.

To help with this research you do not have to do anything else. The research will be done using material from your biopsy that would otherwise be discarded, the blood specimen(s) that you allow to be collected and information from your medical records that is already being recorded to provide your medical care. You do not need to do anything other than give the permissions noted above to help with this important research.

What types of research will be done with your biopsies and medical records?

Understanding what causes cancer, how to treat cancer and the effects of cancer treatment involves studying the material from your biopsies and blood and checking to see how the cancer and its treatment affect you in the future. Because the techniques used to study cancer are constantly improving it is not possible to describe all of them today. However, the types of research will include

1. Analyzing the genetic information in the lymphoid cancer cells and the other cells in your biopsies and in your normal cells.
2. Analyzing the chemical structures on the surface of the lymphoid cancer cells and the other cells in your biopsies.
3. Analyzing the chemicals that the lymphoid cancer cells store within themselves or release into the blood and other body fluids.
4. Recording the results of any treatments that you take for the lymphoid cancer.
5. Recording any future effects of the treatments that you take for the lymphoid cancer.
6. Developing analytical methods, software or other research tools that could be utilized to study cancer as well as other diseases

Other research may be conducted as new and better methods are developed to investigate cancer. All of the research will be Research Ethics Board approved and will focus on cancer and developing better research methods, not on any other medical conditions.

What are the benefits of participating in this research?

There will be no direct benefit to you. The results of the research will not be recorded in your medical record and will not affect your future medical care. However, what is learned from this research will benefit patients with cancers in general and may lead to improved understanding of what causes these diseases and how to treat them more effectively.

The samples and records collected in this research become the sole property of the research investigators conducting the research. Any cell lines, patents, diagnostic tests, drugs or biological products developed directly or indirectly from those samples are also the sole property of the investigators conducting the research. It is possible that this research may eventually lead to the development of a product that can be commercially sold. If such products are developed they will be the result of the entire body of research not just research done on any individual samples. Because of this you will have no right to this property or to any share of profits that may be earned as a result of this research. Any profits that are generated by this research will be used entirely to support cancer research.

What adverse (bad) effects can happen to you if you give permission for this research?

Because you will not have any additional procedures it is very unlikely that you could have any bad effects from this research. The blood test is a standard one using a needle into your vein, just like the blood tests you have had in the past. All records from the research will be kept confidential in password protected computer files that are even more secure than your medical records. The chance of any research results being released despite these precautions is very small and has never occurred from our group's research, which has already involved more than 30,000 participants. We will continue to make every effort to protect your privacy and the confidentiality of these results. Thus, the risk of loss of confidentiality is very low.

Incidental (Unexpected) findings

This study was not designed to find information about your genetic material that could affect your current or future medical care. However, it is possible that researchers will discover information that,

if verified, could affect decisions about your health care. For example, they may find that you have a mutation (change) in a gene that makes you more susceptible to a disease. This is called an incidental finding (discovery of a disease-related gene that the researchers were not looking for) and is considered “actionable” if the finding is one that would lead many people to request certified testing and counselling about what one might do because of the incidental finding. In this sense, “actionable” typically means that certified testing and standardized counselling are available in British Columbia. For example, the researchers may find a mutation is present that markedly increases the risk of breast cancer. Many women would want to know that there is testing and even surgery that could be used to reduce the risk of breast cancer in women with that mutation; thus, it is actionable. On the other hand, the researchers may find a mutation that causes red hair. That type of mutation would not be actionable because its presence is not known to affect one’s health and its presence would not ordinarily lead a person to request counselling. People who have an actionable mutation often wish to have genetic counseling to provide them with information about choices concerning their or their family’s future medical care. If and when the researchers identify an actionable incidental finding, they will inform you that one is present and seek your permission to explain this finding and advise you how to obtain certified testing to be sure it is present and genetic counselling about actions you might take based on the finding. You may choose to give this permission and be informed or you may choose not to hear any more about the finding. The choice is yours. If you decide not to hear about the finding, you may change your mind at any time in the future and can be informed at that time. The cost of the testing needed to verify the incidental findings our research team might uncover is almost always covered by your publicly funded healthcare; however, it is possible that the testing may only be available if you pay for it and the cost may be more than $1000. Whether you have the standard genetic testing done or seek the genetic counseling is entirely voluntary and will be kept confidential by the researchers.

Being told that you have a disease-related gene may cause anxiety or distress or may affect your future employment or access to insurance. On the other hand, it may provide you or your family with information that could be used to prevent future disease. We will only notify you and your doctors that we have made an incidental finding of this kind if you give us specific permission to do so. Because this is a research project rather than a medical test, any incidental findings we make will need to be checked by a certified genetic testing laboratory before any decisions about your healthcare can be made. Your regular physician or a genetic counselor, if needed, will explain the results of the certified genetic test to you and help you decide how to proceed, and whether to inform your family members, who may carry the same genetic abnormality.

How will your confidentiality be protected?

Your confidentiality will be respected. All of the information related to this project that is transferred from any of the health authorities in British Columbia to the investigators will be kept at the BC Cancer Research Center in Vancouver in secure password protected restricted access computer files. No information that discloses your identity will be released or published beyond that. Records or samples that leave the BC Cancer Research Center centre will be identified by a research code only and will not contain any information that identifies you. All information associated with this research will be kept in secure computer files. In order to assure protection of your confidentiality the researchers conducting this research will create a computer file, also known as the "key”, which will be used to connect the information about you to the unique code number assigned to your samples. Only researchers or research

assistants with special training concerning maintenance of confidentiality will be allowed access to the key.

The types of information about you that will be collected include your name, date of birth, PHN, BC Cancer Agency number, details of your medical history, biopsy sites and dates, laboratory tests, reports of imaging studies, types of treatment, other illnesses (if any) that you develop after the lymphoid cancer, tests and measurements from your biopsies. These data, after removal of any information that would reveal your identity, will be associated with the biopsy and blood by way of the unique code number using the "key", described above.

Only the researchers and research assistants conducting this research, independent ethics committees and inspectors from government regulatory agencies will be allowed to inspect the information about you in the research records for this project. Information from this research, without any information that identifies you, may be sent from Canada to other countries, including countries that do not have laws protecting personal data, however, your confidentiality is protected to the best of our ability because you will not be identified in the information that is sent elsewhere.

Your rights to privacy are protected by the federal and provincial laws. These laws provide safeguards respecting your privacy and also give you the right of access to the information about you in these research records and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request.

Will you be provided with the results of this research?

Not individually. The results of this research will be published in medical and scientific journals and you can learn about these research findings by looking for them on the website of the Centre for Lymphoid Cancers. An exception about informing you is described in the previous section on Incidental (Unexpected) Findings.

What will happen to your biopsy specimens and research records about you?

The material from your biopsy will be securely stored indefinitely by the BCCA Cancer Research Center until the sample has been entirely used up. It is important to do this because the research that can be conducted using your biopsy material continuously improves. New questions may be answered in the future with these improved research techniques. Your sample and any information collected from you or your sample for this research, without any information that identifies you, may be sent to other researchers or collaborators, which may require sending this outside of Canada to other countries, to be used for the research described in this consent document.

Will your samples or records be used for other research?

No, your samples and records will only be used for the research described in this consent form.

Can you request that your sample not be used for cancer research?

Yes, your participation in this research is entirely voluntary. If you decide to withdraw or to have your biopsy or blood specimens removed, please write a letter stating your request to the researchers conducting the research. Once you have done this no further research will be conducted using your records and any specimens will be destroyed or returned to their original source (for example, the hospital where the biopsy was obtained); however, any research that had already been conducted and the information that has

already been recorded prior to that time might not be able be withdrawn because the research may already be finished or the specimen may have had your identity removed.

Contact

If you would like to know more about this research project you can read about it at this website: http://www.bccancer.bc.ca/our-research/research-focus/lymphoid-cancer

If you have any questions or desire further information with respect to this research, you can ask the principal research doctor, who is:

Joseph M Connors, MD Telephone 604-675-8000 x 7632

Or, you can speak to the Head of Medical Oncology at the BC Cancer Agency. That person can be reached at (604) 877-6000

If you have any concerns about your rights as a research participant you may contact the Research Participant Complaint Line at the UBC Office of Research Services at the University of British Columbia by email to RSIL@ors.ubc.ca or by phone at (604)-822-8598 (Toll Free: 1-877-822-8598). If you are within the Fraser Health Authority you can contact one of the co-Chairs of the Fraser Health Research Ethics Board with whom you can discuss these rights by calling 604-587-4691.

You have been given two copies of this consent form. Please sign and return one and keep one for your own records.

Participant Consent **PHN _____ BCCA #_____**

- I have read and understood the subject information and consent form and am consenting to participate in the Biology of Lymphoma Study
- 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 affecting my participation in the study and without changing in any way 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.
- I understand that there is no guarantee that this study will provide any benefits to me
- 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.

_____	_____	_____
*Participant's Signature	Printed name	Date
_____	_____	_____
Witness' Signature	Printed name	Date

Participant's address (street, city, province, postal code)

_____

Telephone number _____

Email address _____
(Note: email will only be used to send general information not confidential material)

Directions for returning this consent form:

After you and a witness have signed this form please mail or fax one signed copy to

Lymphoid Cancer Research Coordinator
BCCA Centre for Lymphoid Cancer
BC Cancer Research Centre
675 West 10th Ave
Vancouver, BC V5Z 1L3
Fax: 604-708-2029
Tel: 604-675-8000 x 7632
Email: clc@bccancer.bc.ca
(email is for general use only, do not email confidential material)

Special situations

A Witness/Translator must be independent of the Principal Investigator, their designate or person obtaining consent. The Witness/Translator must attend the consent process if the participant is capable of providing consent but cannot read (for example, is blind or illiterate), or cannot sign or make their mark due to physical impairment.
The Witness/Translator signature is intended to attest to the fact that what is included in this consent document was read to, explained, and apparently understood by the participant, and that their consent was freely given.

1. If this consent process has been done in a language other than that on this written form, with the assistance of a translator (interpreter), please indicate:

Language: _____

Signature of Translator/Interpreter	Printed Name	Date

2. If the participant is able to consent but unable to read or sign due to physical impairment, an Impartial Witness must also attend the consent process and, if able, the participant may sign or make their "mark" below. The Impartial Witness must sign on the Impartial Witness line.

Participant's Signature	Printed name	Date

Signature of Impartial Witness	Printed Name	Date

My signature confirms that what is included in this consent document was read to, explained, and apparently understood by the participant, and that their consent was freely given.

3. If the participant is NOT competent to consent, the participant's Legally Authorized Representative must sign for the participant.

Signature of Participant's Legally Authorized Representative	Printed name	Date