



Patient Name: _____ Patient Received Copy Entered in BMT Serve

LEUKEMIA/BONE MARROW TRANSPLANT PROGRAM OF BRITISH COLUMBIA

Division of Hematology

Subject Information and Consent Form

Hematology Cell Bank of British Columbia

COLLECTION AND TISSUE BANKING OF BLOOD, BONE MARROW MATERIAL, PERIPHERAL BLOOD STEM CELLS OR LEUKAPHERESIS PRODUCT AND COLLECTION OF CLINICAL DATA FROM PERSONS WITH HEMATOLOGIC MALIGNANCIES OR OTHER HEMATOLOGIC DISORDERS FOR RESEARCH ON THE DEVELOPMENT AND TREATMENT OF BLOOD DISEASES

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604-875-4863

Emergency Telephone Number (7 days/week, 24 hours/day): 604-875-4343

Ask for the BMT physician on call

PLEASE NOTE:

GIVE A COMPLETE PHOTOCOPY OF THE CONSENT TO THE PATIENT AND CHECK THE BOX ABOVE

ONLY RETURN ORIGINAL CONSENT SIGNATURE PAGE TO THE RESEARCH DEPARTMENT. Contact: Hematology Cell Bank Coordinator by email at hemcellbank@bccancer.bc.ca; by phone from 8:00 am to 4:00 pm at 604-875-4111 extension 69517

1. INTRODUCTION

Scientists at Vancouver General Hospital, the British Columbia Cancer Agency (BCCA), the University of British Columbia (UBC), the BC Genome Sciences Centre and collaborating researcher scientists are conducting the research that will be described in this information and consent form. These scientists are interested in doing research to better understand how the blood grows and how to correct diseases of the blood. A list of the Primary Research Investigators is provided at the end of this consent form.

You are being invited to take part in this research because you have or are suspected to have a blood disease such as myelodysplasia, a myeloproliferative disorder, bone marrow failure, leukemia, multiple myeloma or lymphoma.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this research. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the research, why the research is being done, what will happen to you during the research and the possible benefits, risks and discomforts.

If you wish to participate, you will be asked to sign this form. If you do decide to take part in this research, you are still free to withdraw at any time and without giving any reasons for your decision. If you do not wish to participate, you do not have to provide any reason for your decision not to participate nor will you lose the benefit of any medical care to which you are entitled or are presently receiving.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

3. WHO IS CONDUCTING THIS RESEARCH?

Scientists at Vancouver General Hospital, the British Columbia Cancer Agency (BCCA), the University of British Columbia (UBC), the BC Genome Sciences Centre and collaborating researcher scientists are conducting the research described in this consent. This research may have been funded by governmental or industrial grants. You are entitled to request any details concerning this funding from the Principal Investigator or Primary Research Investigators of this study. All of the research being conducted will be approved by the Research Ethics Board at the BCCA and UBC. This Board aims to help protect the rights of research subjects.

4. BACKGROUND

Every day the body normally produces billions of new white blood cells, red blood cells and other cells. All of these blood cells are produced in the bone marrow which is located inside most of the bones in the body. The blood cells then move

into the blood stream where they fight infection, provide energy and help clot the blood. Occasionally, something goes wrong with the growth and behavior of these blood cells and a blood disease or cancer develops. Currently not much is known about how normal blood cells become diseased or turn into cancers. In addition, while many blood diseases can be treated, much work still needs to be done to find the safest and most effective cures for most blood diseases.

5. WHAT IS THE PURPOSE OF THIS RESEARCH?

The samples that you donate may be used in several different research projects including research on:

- (1) Normal blood cell production
- (2) Development of methods for ex vivo blood cell production (for use in transplant and/or transfusion)
- (3) Methods of increasing blood production in the body
- (4) Genetic modification of blood cells and leukemic blood cells
- (5) Differences between normal blood cells and leukemic blood cells
- (6) Genetic and cellular events which lead to disease in normal cells
- (7) Which treatments/agents are superior with respect to efficacy & preservation of normal cells
- (8) Hematopoietic Stem Cell Transplant
- (9) Methods of improving transfusion support

Some of this research may involve analyzing genetic events in the blood cells, however no studies are being done to determine whether you or your family members are at risk for developing cancer. The long-term goal of this research is to develop better tests and treatments for patients with diseases of the blood including leukemia and lymphoma.

6. WHAT DOES THIS RESEARCH INVOLVE?

We are inviting you to donate small samples of bone marrow material, blood, peripheral blood stem cells and/or leukapheresis product (white blood cells) for research purposes. The samples will be collected at the time that you are *already* undergoing a bone marrow harvest, bone marrow biopsy, peripheral blood stem cell collection, routine blood collection or during a leukapheresis procedure to reduce white blood cells. They do not require any *additional* procedures be performed.

Additional Blood Sample:

It is important for research purposes to collect blood samples before your treatment begins. It may be necessary for the researcher to request a blood sample from you at a time when you would not already be having blood work drawn. This blood sample would be collected **only once**. You are not obligated to provide these samples at this time and are free to refuse to donate samples outside of a routine sample collection.

All samples will be collected during procedures at the BC Cancer Agency, Vancouver General Hospital, or additional BC hospitals.

Sample Collection:

- If you undergo a bone marrow biopsy, we are requesting that 1 - 2 teaspoons of bone marrow material be obtained for research.
- If you are undergoing a bone marrow harvested procedure, we request 2 – 5 teaspoons.
- If you are having blood drawn, we are requesting that an additional 2-5 tablespoons of blood may be obtained.
- If you are undergoing collection of peripheral blood stem cells or lymphocytes (type of white blood cell) we are asking to obtain 1-2 teaspoons of the cell collection.
- If you have leukemia and need to have the excess white blood cells removed from your body with leukapheresis as part of your treatment, we are asking if we can keep removed cells for research rather than discard them.

Consent-to-Contact:

You may have received this consent form after you agreed to donate additional samples at the time of a diagnostic procedure. At that time you will have signed a consent-to-contact form for optional blood and bone marrow aspirate sample collection. The Hematology Cell Bank of BC coordinator or a research nurse will contact you to discuss the content of this full Hematology Cell Bank of BC consent form. If after reading the full consent form and discussion with the coordinator or research nurse you agree to participate in this research project, you will be asked to complete the signature page of the consent and forward the document to the Hematology Cell Bank of BC coordinator. (Instructions on how to do this will be discussed with you by the coordinator or research nurse.)

If after reading the full consent form and discussion with the coordinator or research nurse you do not wish to participate, the coordinator or research nurse will complete the last page of the consent indicating your wish not to participate. You may also provide an email with these instructions if you prefer. At this time all samples previously collected will be destroyed.

There may be times when you undergo a diagnostic procedure and blood or bone marrow material is collected for testing. After the diagnostic procedure is completed a portion of the material is usually discarded. That material may have been collected prior to you signing this consent form. By signing this consent form you agree to donate to the Hematology Cell Bank of BC, blood or bone marrow material already collected that would normally be discarded.

If you are donating peripheral blood stem cells or bone marrow harvested stem cells for your transplant and the transplant does not take place as planned those samples will be kept frozen in storage for 7 years. Following the 7 year period those samples are destroyed. You can choose to have those samples donated to research after the 7 year period if you wish. By signing this consent form you agree to donate collected stem

cells to the Hematology Cell Bank of BC for research following the 7 year period of storage.

Sample and data sharing

The HCB samples and information learned from analyzing them may be shared with other researchers around the world conducting 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 traditionally used information that identifies you such as your name, address, telephone number or social security number. Access to this protected information will be allowed for projects using the information for research relevant to the normal hematology biology and cancer.

7. HOW LONG WILL SAMPLES BE COLLECTED AND STORED?

If you decide to participate in this research and sign this consent form, then research samples will be collected for the duration of the time you receive treatment and follow-up care for your disease. This may involve a sample collected when you are first diagnosed and/or a sample collected at a later follow-up appointment, or it may involve the collection of blood samples weekly or monthly. You will be informed, at the time of your procedure, that a sample is being collected for the Hematology Cell Bank of BC.

Some of the samples may be used immediately but others may be frozen for days to years before they are used for research. Usually such samples obtained for research are only kept for a specific amount of time, however, because research continues to improve and new research questions become important the researchers are seeking your permission to keep the samples indefinitely or until they are used up. The samples will be used for research purposes only and will not be sold. All samples collected will be sent to the Stem Cell Assay Laboratory at the BC Cancer Research Centre and will be stored there.

8. COLLECTION OF MEDICAL INFORMATION

Some of this research will involve the collection of medical information about you. You are being asked to give your permission for the collection of information from your medical charts (at VGH, BCCA, BCCA Hospital sites, St. Paul's Hospital and from additional BC hospitals) for the purposes of the research described in Section 5. Information collected may include: age; gender; ethnic background; diagnosis; date of diagnosis; type of treatment; date of remission; type of treatment for disease; date of relapse; bone marrow biopsy results; relevant blood work results. This is not a complete list. This list is an example of the type of information that may be collected. Only trained researchers will collect this information. Every effort will be made to respect your confidentiality as described in Section 19.

If you initially signed a consent-to-contact form, no medical information will be collected from you until you have had the opportunity to read and sign this full consent form. Once you have signed this form or indicated by email your wish to participate in donating samples to the Hematology Cell Bank of BC requests for medical information will be submitted in writing to the hospital providing your research sample by the Hematology Cell Bank of BC coordinator and will require the hospital's approval for release. All medical data obtained from your treating hospital will follow the guidelines to ensure your privacy outlined in section 19 of this consent.

9. WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

There may be side effects from the bone marrow aspiration, harvest, leukapheresis procedure or blood drawing procedure but these will be explained to you in another consent form that tells you about the risks and benefits of the procedure. The form that you are reviewing now only refers to donating some of the blood, bone marrow material, or cells collected from these procedures for research purposes.

If you are donating blood or bone marrow to a person undergoing a bone marrow transplant or other treatment, removal of the small sample for research will not affect the care of this person.

There are possible non-physical risks associated with taking part in this study. For example, although extremely unlikely, disclosure of genetic or tissue marker research data could in theory result in discrimination by employers or insurance providers toward you or your biological (blood) relatives. There also may be other privacy risks that we have not foreseen. We believe that the risks to you and your family are very low. Additionally, the chance that research data would be released is estimated to be small.

10. WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS RESEARCH?

You will not directly benefit from this research. We hope that the information learned from this research can be used in the future to benefit other people with a similar disease. Research done with your blood or bone marrow material samples may help to develop new products in the future.

11. HOW MUCH OF MY TIME WILL IT TAKE TO PARTICIPATE?

Aside from the time it takes for you to read this consent form and ask questions regarding the study, participation in this research will not require any time on your part.

12. HOW LONG WILL MY CONSENT TO PARTICIPATE LAST?

If you decide that you would like to participate in this research you will be asked to sign this consent form. Once you have signed this consent form research samples will be taken as described in Section 6. Samples and clinical information for this

research will be collected throughout the entire time that you receive treatment/and or follow-up through the Leukemia/BMT Program of BC (at Vancouver General Hospital and/or the BC Cancer Agency). By signing this consent form you are agreeing to the collection of samples and clinical information for this entire time period (which may last several years depending on your situation). (As stated in Section 6, your samples may be kept indefinitely at the Hematology Cell Bank of BC for future research.)

If you decide to participate in this research and sign this consent form, you will not be asked for your consent again. Please consider carefully if you are willing to donate samples and clinical information for this research over the entire period that you receive treatment and follow-up through the Leukemia/BMT Program of BC (at Vancouver General Hospital and/or the BC Cancer Agency). It is important to be aware that you may withdraw from this research at any time.

You are encouraged to discuss this research and the collection of samples with your Leukemia/BMT physician at any time during your treatment and follow-up if you have any questions or concerns.

13. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You may withdraw from this research at any time and request that the research samples that have been collected be destroyed, unless those samples have already been released to a researcher for use. If you withdraw from this research no further samples will be obtained and no further information from your medical charts will be collected. If you decide to do this, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected. In order to withdraw from this research you must notify the Hematology Cell Bank Coordinator at 604 875-4111, extension 69517 or the Principal Investigator, Dr. Raewyn Broady, at 604-875-4863.

Any information that has been gathered from your samples and medical chart(s) prior to notification of withdrawal will not be destroyed.

14. WHAT HAPPENS IF SOMETHING GOES WRONG?

If you become injured or unexpectedly ill as a consequence of participation in this research, your medical condition will be evaluated and medical care will be provided by one of the investigators or you will be referred for appropriate treatment.

15. LEGAL RIGHTS

Signing this consent form in no way limits your legal rights, nor rights to the best medical care available to you.

16. WHAT HAPPENS AFTER THIS RESEARCH IS FINISHED?

You will not be directly notified of the outcome of this research or of your specific results. Once the research is completed, it may be published in scientific journals or presented at scientific conferences. When that happens, the publications containing anonymous data will be available in the public domain accessible by the general public. Information about the published research projects the Leukemia/BMT program has supported are listed on the Leukemia/BMT Web site at: www.leukemiabmtprogram.com.

17. WHAT WILL THIS RESEARCH COST ME?

It will not cost you any money to participate in this research.

18. WILL I BE PAID FOR PARTICIPATING IN THIS RESEARCH?

You will not be paid for donating any samples for research purposes. There are no plans to pay you if this research results in a commercial product.

19. WILL MY TAKING PART IN THIS RESEARCH BE KEPT CONFIDENTIAL?

Your confidentiality will be respected to the extent permitted by applicable laws and regulations and your medical and study records will not be publicly available. No information that discloses your identity will be released or published without your specific consent to the disclosure. Your identity will not be used in any reports about the study. Records or samples that leave this centre will be identified by a study code only. All information associated with this study will be kept behind locked doors or in secure computer files. Reports about any research done with your samples will not be given to you or your doctor. These reports will not be put in your medical records. The research using your samples will not affect your care.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the researcher and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor or the UBC BCCA Research Ethics Board.

If your blood, bone marrow material or cell samples are stored, they will be labeled with a code that will not identify you by name, birth date or initials. In the future, people who do research with your sample may need to know more about your health. The researchers coordinating this study may provide those reports about your health to the researcher. Every researcher who accesses samples donated to the Hematology Cell Bank of BC signs a confidentiality agreement that stipulates they will not disclose your name or any other identifying details publicly. Researchers who request access to your medical records, in addition to signing a confidentiality agreement, will be doing so only after approval from a research ethics board, which requires that proper procedures are followed to protect your privacy. Any data that is shared by collaborating researchers who have not signed a confidentiality agreement will have your name and any other identifying data removed.

Your confidentiality will be respected.. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of granting agencies, inspectors from government regulatory agencies such as Health Canada, and the BCCA Research Ethics Board/independent ethics committees for the purpose of monitoring the research. No records which identify you by name or initials will be allowed to leave the Investigators' offices by these official representatives.

Information from this research without any traditional information that identifies you, may be sent from Canada to other countries, including countries that do not have laws protecting personal data. However, we will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

20. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THIS RESEARCH DURING MY PARTICIPATION?

If you have any questions or desire further information about this research before or during participation, you can contact the Hematology Cell Bank Coordinator at 604 875-4111, extension 69517 or Dr. Raewyn Broady at 604-875-4863.

21. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT DURING THIS RESEARCH?

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

22. Primary Research Investigators: Vancouver General Hospital, UBC Department of Medicine, BC Genome Sciences Centre, BC Cancer Agency, St. Paul's Hospital, Women's and Children's Hospital and additional BC Hospital centres.

Dr. Yasser Abou Mourad	Dr. Peter Lansdorp
Dr. Michael Barnett	Dr. Heather Leitch
Dr. Raewyn Broady	Dr. James Lim
Dr. Joe Connors	Dr. Stephen Nantel
Dr. Mike Delorme	Dr. Sujaatha Narayanan
Dr. Connie Eaves	Dr. Thomas Nevill
Dr. Donna Forrest	Dr. Willie Pewarchuk
Dr. Lynda Foltz	Dr. Maryse Power
Dr Alina Gerrie	Dr. Khaled Ramadan
Dr. Tanya Gillan	Dr. Gregory Reid
Dr. Lawrence Haley	Dr. David Sanford
Dr. Jason Hart	Dr. Kirk Schultz
Dr. Donna Hogge	Dr. Kevin Song
Dr. Robert Holt	Dr. Peter Stirling
Dr. Keith Humphries	Dr. Heather Sutherland

Dr. Xiaoyan Jiang
Dr. Aly Karsan
Dr. Gerald Krystal
Dr. Wendy Lam

Dr. Fumio Takei
Dr. Cynthia Toze
Dr. Andrew Weng
Dr. Angela Brooks-Wilson
Dr. Adrian Yee

23. SUBJECT CONSENT TO PARTICIPATE

By signing this consent form I am agreeing to the collection of samples (as described in Section 8) and clinical information for the entire time period that I receive treatment and/or follow-up through the Leukemia/BMT Program of BC. This time period may last several years depending on my situation.

I understand that participation is entirely voluntary. I may refuse to have samples and clinical information collected from me. I can withdraw my permission to use my samples and clinical information at any time. If I withdraw this permission to use my samples they will be destroyed unless already released to a researcher for use. Although I cannot have access to test results directly related to my tissue samples, I may ask questions about the type of research being done. By signing and dating this consent form I am agreeing to participate in the research described in this consent form. I agree to the use of samples collected from me for research. I agree that information can be collected from my medical chart(s) for the purposes of the research described in Section 5. I also agree to the storage of the samples I donate as described in Section 7. I will receive a signed copy of this consent form.

Subject's Signature Printed name Date

Subject Date of Birth: _____

Investigator's Signature or
Delegate's Signature Printed name Date

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

Language: _____

Translator's signature Printed name Date

Addendum:

I _____ agree to be contacted in the future to discuss whether I
(subject to print name)

will give permission for my specimens to be used for research projects other than those discussed in this consent. I agree to be contacted in the future to discuss whether I will give permission for information to be collected from my medical chart(s) for research projects other than those discussed in this consent.

Yes No Initial _____

Hematology Cell Bank of BC

Complete the information below if the prospective subject does not want to participate in this research:

Patient _____ DOB _____
Print name DD-MMM-YYYY

declined to participate in the Hematology Cell Bank Project on _____.
DD-MMM-YYYY

Name of Person who offered participation/provided consent form:

Physician/research coordinator/research nurse name (printed)

Signature of Physician/research coordinator/research nurse

Date (DD-MMM-YYYY)

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- Once this consent form is completed provide a complete photocopy to the patient and contact the Hematology Cell Bank Coordinator to collect consent or place in the Hematology Cell Bank folder for pick up.
 - Do not maintain the original consent in the patient chart