Patient Name: _____ Patient Received Copy☐ Entered in BMT Serve☐

Division of Hematology
2775 Laurel Street, 10th Floor
Vancouver, BC V5Z 1M9
Phone: 604.875.4863
Fax: 604.875.4763
www.leukemiabmtprogram.com

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 AND/OR PERIPHERAL BLOOD STEM CELLS AND COLLECTION OF CLINICAL DATA FOR RESEARCH ON BLOOD GROWTH AND BLOOD DISORDERS

Principal Investigator: Dr. Raewyn Broady,
UBC Department of Medicine
British Columbia Cancer Agency (BCCA)
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 THE DONOR A COMPLETE PHOTOCOPY OF THE CONSENT AND CHECK THE BOX ABOVE

RETURN THE ORIGINAL CONSENT 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), BC Genome Sciences Centre and collaborating research 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 researchers and clinicians involved in the research discussed in this consent are compiled at the end of this consent.

You are being invited to take part in this research because you have healthy blood.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary; 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 study, 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 study, 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 THE STUDY?

Scientists at Vancouver General Hospital, the British Columbia Cancer Agency (BCCA), the University of British Columbia (UBC), BC Genome Sciences Centre and collaborating research scientists are conducting the study described in this consent. The research being performed as part of this study 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. 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. While much is known about how blood cells grow and carry out these important jobs, there are still many things that we do not understand about the blood system, including how blood cells grow or turn in to cancer cells.

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 in general for patients with diseases of the blood like leukemia.

6. WHO CAN PARTICIPATE IN THIS RESEARCH?

Anyone can participate in this study that has a healthy blood system.

7. WHAT DOES THIS RESEARCH INVOLVE?

Sample Collection:

- We are inviting you to donate a small sample (1-2 teaspoons) of the peripheral blood stem cells that will be collected from you for hematopoietic stem cell transplant.
- We are also asking that you donate up to 15 - 20 mL of blood (3 - 4 teaspoons) prior to the collection of your peripheral blood stem cell or bone marrow harvest.
- If you are donating stem cells at the time of a bone marrow harvest, we request 2 – 5 teaspoons from the harvested material.

All of these samples will be collected at the time that you are *already* undergoing a bone marrow harvest, peripheral blood stem cell collection or routine blood collection. They do not require any *additional* procedures be performed.

Additional blood sample: It may be necessary for the researcher to request a blood sample from you when you are not having blood work drawn. This would be requested **only once.** You are free to choose not to donate samples outside of a routine collection.

There may be times when you undergo a diagnostic procedure and blood or bone marrow material is collected. 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 the remaining blood or bone marrow material already collected and usually discarded.

If you are donating peripheral blood stem cells or bone marrow harvested stem cells for 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 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.

8. 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 project. This may involve a sample collected when you are first donating samples or at a later follow-up appointment. 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 Hematology Cell Bank of BC and will be stored there located at the Stem Cell Assay Laboratory at the BC Cancer Research Centre.

9. COLLECTION OF MEDICAL INFORMATION

Some of this research may involve the collection of information about you. You are being asked to give your permission for the collection of information from your medical charts (at VGH and/or BCCA) for the purposes of the research described in Section 5. Information collected may include: age; gender; ethnic background; health history. 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 Section19. 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. No data that identifies you will be disclosed publicly.

10. 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 this research, participation in this research will not require any time on your part.

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

There may be side effects from harvest 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 or stem cell/bone marrow material 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.

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.

12. WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You will not directly benefit from this study. We hope that the information learned from this research can be used in the future to benefit people with cancer and other blood diseases. Research done with your samples may help to develop new products in the future. Any discoveries from this research are the property of the University of British Columbia and the BC Cancer Agency so that if any commercial products are developed from this research, the University of British Columbia and the BC Cancer Agency will assert all rights arising from use of the samples you have donated. There are no plans to pay you if the research done in this study does result in a commercial product.

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 study at any time and request that the research samples that have been collected be destroyed.

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 your 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 against the sponsor, investigators, or anyone else.

16. WHAT HAPPENS AFTER THIS RESEARCH IS FINISHED

You will not be directly notified of the outcome of the studies 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. Any discoveries from this research are the property of the University of British Columbia and the BC Cancer Agency so that if any commercial products are developed from this research, the University of British Columbia and the BC Cancer Agency will assert all rights arising from use of the samples you have donated. There are not plans to pay you if this research results in a commercial product.

19. WILL MY TAKING PART IN THIS STUDY 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 sponsor/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 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 give those reports about your health. 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. 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 investigating agency will be able to remove documentation from Investigator's offices that identifies you.

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 study before or during participation, you can contact 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: UBC Department of Medicine, Vancouver General Hospital, BC Cancer Agency, St. Paul's Hospital, Women's and Children's Hospital, BC Genome Sciences Centre and additional BC hospital centres.

Dr. Yasser Abou Mourad
Dr. Michael Barnett
Dr. Raewyn Broady
Dr. Joe Connors
Dr. Mike Delorme
Dr. Connie Eaves
Dr. Donna Forrest
Dr. Lynda Foltz
Dr. Alina Gerrie
Dr. Tanya Gillan
Dr. Lawrence Haley
Dr. Jason Hart
Dr. Donna Hogge
Dr. Robert Holt
Dr. Keith Humphries
Dr. Xiaoyan Jiang
Dr. Aly Karsan
Dr. Gerald Krystal
Dr. Wendy Lam
Dr. Peter Lansdorp
Dr. Heather Leitch
Dr. James Lim
Dr. Stephen Nantel
Dr. Sujaatha Narayanan
Dr. Thomas Nevill
Dr. Willie Pewarchuk
Dr. Maryse Power
Dr. Khaled Ramadan
Dr Gregory Reid
Dr. David Sanford
Dr. Kirk Schultz
Dr. Kevin Song
Dr. Peter Stirling
Dr. Heather Sutherland
Dr. Fumio Takei
Dr. Cynthia Toze
Dr. Andrew Weng
Dr. Angela Brooks-Wilson
Dr. Adrian Yee

23. SUBJECT CONSENT TO PARTICIPATE

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 destroyed. 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 8. I will receive a signed copy of this consent form.

_____	_____	_____
Subject's Signature	Printed name	Date

Subject's 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:

Donor _____ **DOB** _____
Print name *DD-MMM-YYYY*

declined to donate to the Hematology Cell Bank 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)

- **Once this consent form is completed provide a complete copy to the donor and contact the Hematology Cell Bank Coordinator to collect the consent or place in the Hematology Cell Bank of BC binder for pick up.**
- **Do not maintain the original consent in the donors chart.**