



LEUKEMIA/BONE MARROW TRANSPLANT PROGRAM OF BRITISH COLUMBIA
Division of Hematology

Study Information and Consent Form

Biobank:

HEMATOLOGY CELL BANK OF BRITISH COLUMBIA

A collection of tissue and data

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 (AND FROM PERSONS WITH NORMAL BLOOD, BONE MARROW MATERIAL, AND/OR PERIPHERAL BLOOD STEM CELLS) FOR RESEARCH ON THE DEVELOPMENT AND TREATMENT OF BLOOD DISEASES

Biobank Custodian: Dr. David Sanford

UBC Department of Medicine

British Columbia Cancer

604-875-4863

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 HEMATOLOGY CELL BANK COORDINATOR

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PURPOSE

A biobank collects, stores and gives out human samples (tissue, blood, fluids, stem cells, etc) and related health information, to researchers, for the purpose of future research. You are being invited to donate your samples and/or information to the biobank. Researchers who are looking for new ways to detect, treat and maybe even prevent cancer, will access the samples and information that are stored at the Hematology Cell Bank of British Columbia (HCB) to conduct their own studies. Because cancer research is always progressing, it is unknown at this time what future research will be done on your samples or information, but some of these studies may lead to new products, such as drugs or tests for cancer, or may look at genes (which carry information needed to build and operate a human body) and how genes affect health or response to treatment. Some of collected samples may be transferred to mouse or animal models to simulate cancer biology and learn more about disease detection, treatment and/or prevention.

PARTICIPATION

You may participate in this biobank if you are 18 years of age or older, and you have received or will be receiving medical care at VGH/BC Cancer.

Your participation is entirely voluntary. Please take as much time as you need to decide. The decision you make, whether to participate or not, will have no effect on your medical care.

WHAT IS INVOLVED?

If you decide to participate in this biobank, research samples will be collected for the duration of time you receive treatment and follow-up care for your disease. This may involve samples collected at diagnosis, and/or a sample collected at a later follow-up appointment or it may involve the collection of blood samples weekly or monthly.

You may receive this consent form after you agreed to donate additional samples at the time of a diagnostic procedure. At that time you will verbally consent to HCB Witness of Verbal Consent for optional blood and marrow aspirate collection

Tissue

No special test or procedure is required to donate your tissue – bone marrow material, blood stem cells and/or leukapheresis product (white blood cells). At the time when you are already undergoing a bone marrow harvest, bone marrow biopsy, peripheral blood stem cell collection or leukapheresis procedure to reduce white blood cells, your hematologist or hematopathologist will remove whatever tissue is required for your diagnosis/treatment. Whenever possible, the biobank samples will be collected as an extra bone marrow material (1-2 teaspoons), harvested stem cells (2-5 teaspoons), peripheral stem cells/lymphocytes (1-2 teaspoons) or excess white blood cells removed from your body with leukapheresis procedure (usually discarded).

Some of removed tissue used for diagnostic purposes will be stored by the Department of Pathology for future care and diagnosis. The remainder is usually discarded, but the Hematology Cell Bank would like to collect and store this remaining material for researchers to use in ongoing and future projects. The Hematology Cell Bank may also collect some of the material stored by the Department of Pathology in the future, but

only if a Pathologist determines that this material can be used without affecting your future care.

Blood

Blood samples may be collected in a single collection at the time you are already having blood drawn for clinical purposes. Whenever possible, the biobank samples will be collected as an extra blood sample (about 2-5 tablespoons of blood) at the same time as blood samples are being obtained from a vein in your arm for your clinical care. If we are unable to obtain an extra sample when your clinical samples are being obtained then we may ask you to provide a blood sample just for this biobank. This blood sample would be collected **only once** and is optional. You may still donate to the biobank even if you do not want to provide a blood sample outside of a routine sample collection.

Information

We will ask you for some basic information. This will include things like name, age, sex, and race or ethnic group. We will collect information from your medical records including those records at VGH, BC Cancer, BC Cancer Hospital sites, St. Paul's Hospital and/or additional BC hospitals. Information may include results of tests, medical procedures, images (such as X-rays), and medicines you take.

DURATION OF STORAGE

The samples will be stored securely and indefinitely until they have been entirely used up. It is important to do this because the research that can be conducted using your marrow, blood, stem cells and related clinical data continuously improves.

BENEFITS

You should not expect to get direct health benefits from donating to this biobank. Results obtained from research studies that include your biological samples, or data will not be given to you or entered into your medical record. The main reason you may want to take part is to help researchers find new ways to prevent, detect, and treat cancer.

RISKS

Physical Risks

There are no physical risks to you when the Hematology Cell Bank of BC collects tissue left over and/or extra samples from clinical treatment or procedure you are undergoing except what is with procedure or treatment itself. In most instances, the Hematology Cell Bank of BC obtains blood samples only when a clinical sample is obtained. But when blood is drawn, you may feel brief pain or have some bruising from the needle. Infection, light-headedness, and fainting are also possible, but unlikely.

CAN YOU STOP TAKING PART IN THE BIOBANK?

Participation in this biobank is entirely voluntary. You can withdraw your sample(s) at any time for any reason without any consequences to your medical care. If you want to withdraw your samples, call the Biobank at 604-875-4111 extension 69517, the Hematology Cell Bank Coordinator to let us know. We will arrange to meet with you or we will send you a form with several options so you can tell us what to do with your unused sample(s).

Please note that we cannot get back samples or information that we have already given out to researchers.

PRIVACY & CONFIDENTIALITY

Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law.

However, there is a risk that someone could get access to the information we have stored about you, it could be revealed inappropriately or accidentally, and the risk of someone identifying you may increase in the future as people find new ways of tracing information. Depending on the nature of the information, such a release could upset or embarrass you, or be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse in Canada, but they may not give full protection, and laws in other countries may not be as strict as those in Canada, so when your information and samples are sent to places outside of Canada, you may not be afforded the same rights. We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us, and we will make every effort to protect these as described below.

Study-related data and coding:

- All information gathered for use in the biobank is referred to as the 'study-related data'. This data may include your medical records, biological materials, genetic information, etc. The study-related data will be transformed into datasets that can be analyzed. You will be assigned a unique code that will be used to track your study-related data. This unique code does not include any personal information that could identify you, and will be used on all study-related data that leave BC Cancer or VGH unless otherwise specified in this form (this is referred to as 'coded data').

If you initially verbally consented, 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, all medical data that will be obtained from your treating hospital will follow the guidelines to ensure your privacy & confidentiality outlined in this consent.

- Coded data (including genetic information) resulting from analyses being done on samples from this biobank may be pooled and shared with researchers from around the world for future studies that are unknown at this time. It may also be added to public databases, published, or presented at scientific meetings. The aim of these future studies is to benefit people by improving our understanding of health conditions like cancer.

WHO WILL HAVE ACCESS TO YOUR SAMPLES AND STUDY-RELATED DATA?

Researchers can ask to study the materials stored in the biobank. This includes researchers from BC Cancer, as well as from other universities, the government, and drug- or health-related companies. Some researchers will be from Canada, and some may be from other countries around the world. All researchers applying will be required to submit details of their project and a science committee at the biobank will review each

request. There may also be an ethics review. This kind of review is to make sure that your welfare and rights are protected. HCB samples will only be released to Research Ethics Board approved projects. Research records and medical records identifying you may also be inspected in the presence of the Investigator or his or her designate by representatives of Health Canada and the BC Cancer Research Ethics Boards for the purpose of monitoring the research.

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.

COSTS, REIMBURSEMENT and COMPENSATION

There are no costs to you for taking part in the Biobank. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

Your biological samples and information collected for this biobank will not be used for commercial re-sale. Researchers or companies who receive material and/or data must agree that material and/or data will not be sold or used for commercial purposes and will only be used to support cancer research. Researchers may be charged a fee to help cover some of the costs of storage, release, and overall operation of the Hematology Cell Bank of BC.

WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS?

If you have any questions or desire further information with respect to this study before or during participation, you may contact the Nerkeza Andjelic Project Coordinator at 604-875-4111 extension 69517

You can contact the BC Cancer Research Ethics Board (REB) about your rights as a research participant at reb@bccancer.bc.ca, or 604.877.6284. Please provide the reference number H19-01373 when contacting the REB so the staff can better assist you.

Signing this consent form in no way limits your legal rights against the investigators, or anyone else involved in this biobank.

You will be given a copy of this signed and dated consent form prior to participating in this biobank, and a copy will also be included in your biobank records.

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

Dr. Yasser Abou Mourad
Dr. Raewyn Broady
Dr. Helen Bruyere
Dr. Mike Delorme
Dr. Connie Eaves
Dr. Donna Forrest
Dr. Lynda Foltz
Dr. Alina Gerrie
Dr. Lawrence Haley
Dr. Jason Hart
Dr. Kevin Hay
Dr. Robert Holt
Dr. Xiaoyan Jiang
Dr. Aly Karsan
Dr. Gerald Krystal
Dr. Florian Kuchenbauer
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. Ly Vu
Dr. Andrew Weng
Dr. Angela Brooks-Wilson
Dr. Jennifer White
Dr. Adrian Yee

SIGNATURES

BIOBANK – HEMATOLOGY CELL BANK OF BC

My signature on this consent form means:

- I have read and understood the information in this Study Information and Consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this biobank is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw my samples at any time unless they are already released to researchers, and that this will not change the quality of care that I receive.
- I understand and accept that there will not be a benefit to me as a result of participating in this biobank.
- I authorize access to my medical records, biological material, and/or genetic information, as well as my study-related data as described in this consent form.
- I am not waiving any of my legal rights by signing this Study Information and Consent Form.
- I hereby consent to participate in this biobank as described in this Study Information and Consent Form.

In addition, please specifically address the below:

- I agree to be contacted in future to discuss participation in other research.

Yes _____ (Initials) No _____ (Initials)

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Signature of Participant

Printed Name

Date

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Signature of Person Conducting the Consent Discussion

Printed Name

Date

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

Language: _____

Was the participant assisted during the consent process in one of ways listed below?

Yes No [Note: For typical situations where the person conducting the consent discussion simply reads the consent with the participant to ensure that informed consent is properly obtained, check “no”.]

If yes, please check the relevant box and complete the signature space below:

The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read).

The person signing below acted as an interpreter for the participant, during the consent process (please check if an interpreter assisted during the consent process).

Signature of Person Assisting
in the Consent Discussion

Printed name

Date