SUBJECT INFORMATION and CONSENT FORM

BC Cancer Agency CARE & RESEARCH	**Tumor Tissue Repository (BCCA-TTR)** **- a collection of tissue and data for research**

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Tel. (250) 519-5500
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Why are you being asked to participate in this study?
You are being invited to participate because you have previously had, or will soon have, a medical procedure for treatment of a tumor. You are being asked to donate your tissue (surgical tissue, biopsy tissues, fluids) and clinical information to the BC Cancer Agency's Tumor Tissue Repository (BCCA-TTR) to support cancer research.

Your participation is voluntary and you may decide to participate or to withdraw at any time. Your decision to participate will not affect your treatment in any way and your doctors will continue to provide the best available treatment for your disease. The purpose of this form is to provide you with information about the BCCA-TTR and to ask if you will agree to participate.

What is the BCCA-TTR?
It is a biobank that is a collection of tissues and clinical information donated by people who have had a medical procedure such as surgery to treat a tumor. The BCCA-TTR provides a resource for a range of cancer research projects at the BCCA, and also across Canada and internationally. Each donation can support several research projects.

What tissues will the BCCA-TTR collect and how will it obtain my tissues?
During the assessment of each specimen removed at the time of a medical procedure, small samples are normally taken by Pathologists in order to make a diagnosis. These samples are then stored in the Department of Pathology for your future clinical care. Excess tissue not needed for your clinical care often remains, both after the procedure when small samples have been taken to make a diagnosis, and then after the diagnosis, from amongst the samples that are taken and stored by Pathologists. The BCCA-TTR collects these excess tissues and processes and stores these for research,

after the medical procedure and after the Pathologists have determined that they are not required by the hospital for your diagnosis.

What information will the BCCA-TTR collect and store?
The BCCA-TTR collects information on the tissue, clinical information from the medical record, and personal information that is relevant to the disease. The tissue information includes the composition of the tissue, the size and type of tumor (or, in the case of fluids, the appearance and amount of fluid). The clinical information includes the subject's age, the results of clinical tests such as x-rays, the type of treatment, and follow-up information about the outcome of the treatment. The personal information includes the subject's name, age and symptoms. This information is stored as coded tissue samples and coded paper and computer files in a secure location within the BCCA Vancouver Island Center and within the BCCA Vancouver Research Center. The tissue and information will be stored indefinitely and the measures taken by the BCCA-TTR to ensure the security and integrity of your donation will be reviewed annually by the UBC BCCA Research Ethics Board.

What will be released to researchers and for what research projects?
Researchers may obtain the materials only if they apply to the BCCA-TTR through a formal scientific review process and if they also obtain approval for their research project from the UBC BCCA Research Ethics Board or a properly constituted Research Ethics Board. Research Ethics Boards review research projects to make sure that they follow standards of fairness in protecting the rights of research subjects. The materials provided include tissue, products of the tissue, and information that are coded so that they are anonymous, meaning that they cannot be linked to the individual subject by the researcher or anyone else. The research studies will involve testing tissue samples for features of cells, including the structure and expression of genes, and relating these features to the associated information about the subject and the disease, to gain a better understanding of how tumors develop, grow, spread, and how tumors can be better treated. The studies may also involve testing tissue samples and analyzing information for teaching, education, and internal program evaluation.

If any other type of research study is proposed, such as one that involves hereditary genetic testing with your tissue (to see if cancer or other diseases run in your family) you will be contacted and asked to give your permission for this type of hereditary genetic testing. These genetic tests will not be done without your permission.

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 dealing with protection of information may not be as strict as in Canada. However, all study data and samples, that might transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the transfer of your information and samples, to organizations located outside of Canada.

What will I have to do if I agree to participate?

1. No special test or procedure is required to donate your tissue. If there is any excess tissue not needed for your clinical care, then this tissue will be transferred to the BCCA-TTR. Excess tissue samples may be related to a current medical

procedure or may have been taken at the time of a medical procedure in the past and then stored in the Department of Pathology. Should your tumour recur and require future medical procedures, then excess tissue at this time will also be transferred to the BCCA-TTR.

2. Information will be collected regarding the diagnosis and type and stage of your tumor, as well as your personal medical history such as your age and symptoms. This information will be collected directly from you and from your medical records. These medical records may include those in your family doctor's office, the hospital, the BCCA, and laboratories that have participated in your care. As it is important to know the outcome of your treatment, we will also request updates on this information from the same sources in the future.
3. A blood sample of up to approximately two tablespoons (30 mL) will be drawn from a vein in your arm. This blood sample or products such as serum will be stored with your tissue. This blood sample is optional and if you are uncomfortable about this then you may choose not to provide it but to still participate in the BCCA-TTR.
4. You may be requested to complete a questionnaire. This is optional and you may choose not to complete the questionnaire but to still participate in the BCCA-TTR.

What will be done to protect your confidentiality?

Information that links your identity to your samples and your records must be maintained to enable the project to update your record with additional clinical information concerning your status and the outcome of your treatment, and also to enable the project to withdraw your tissue and information if you wish to withdraw your consent in the future. However, this information that links your identity to the sample or the record will not be released to researchers. Identifying information will only be available to the Director of the BCCA-TTR and members of the BCCA-TTR staff, and then only when necessary to update your record. Research records and medical records identifying you may also be inspected by representatives of Health Canada, the U.S. Food and Drug Administration and the UBC BCCA Research Ethics Board for the purpose of monitoring research. However, no records that identify you will be allowed to leave the BCCA Vancouver Island Center and BCCA Vancouver Research Center. These organizations have policies of strict confidentiality and the individuals inspecting your records must sign a BCCA confidentiality form (the form is not applicable to Health Canada or U.S. Food and Drug Administration officials, who have the legal right to inspect health records and are bound to confidentiality by specific laws). Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent. Your identity will not be used in any research reports. Records or samples provided to researchers will be identified only by an anonymous code. All information associated with the BCCA-TTR will be kept behind locked doors or in secure computer files. The BCCA-TTR operates with security standards that include organizational policies and a commitment to privacy that is embodied in all standard operating procedures, physically secure areas within the BCCA, and technological measures such as passwords, encryption, and anonymization of data. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure 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 and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the Director of the BCCA-TTR or the UBC BCCA Research Ethics Board.

What are the risks?
There are no physical risks to you that arise from the collection of a sample of tissue/fluids from your medical procedure. There may be mild pain or discomfort from the collection of your blood sample. The amount of blood taken should not affect your overall well-being. There may be a risk that your privacy could be compromised. The staff of the BCCA-TTR will strive to minimize this risk of loss of privacy by ensuring that your donated samples and data are stored within the BCCA-TTR using code numbers and practices that maintain confidentiality and security standards. Samples and data will only be released for research under anonymous code numbers.

What are the benefits?
There is no direct benefit to you from participating in this project. Results obtained from research studies that include samples of your tissue or blood and data will not be given to you or entered into your medical record. The research that will be done with your samples may help other people in the future who have either the same type of tumor that you have or another type.

Will I receive compensation?
You will receive no payment or compensation for your participation in the BCCA-TTR. In the long-term, if a diagnostic or therapeutic product or service is developed, you will not receive a financial benefit.

Will anyone else receive remuneration?
No tissue, blood or clinical information is used for commercial purposes. Researchers may be charged a user fee to cover some of the costs of storage and release and operation of the BCCA-TTR. Researchers who receive material must agree that no tissue or blood will be sold or used for commercial purposes and will only be used to support cancer research.

How can I withdraw in the future?
If you wish to withdraw your consent, you may contact the Director at any time. The BCCA-TTR will withdraw and destroy all of your tissue and blood samples that remain in the BCCA-TTR. We will also destroy all of your personal and medical information in our files. We will retain only a record of who had access to your tissue and information, a reference to any studies that have used your tissue and information, and the research data obtained.

Contacts:
If you have any questions or desire further information with respect to this study, you may contact the BCCA-TTR Project Nurse, Jodi LeBlanc (250-519-5713), or, the Principal Investigator, Dr. Peter Watson (250-519-5700).

Or, you may speak to the Vice President Cancer Care at the BC Cancer Agency Telephone (604) 877-6000 x 2738.

If you have any concerns about your treatment or rights as a research subject you may contact the Research Subject Information Line at the UBC Office of Research Services at the University of British Columbia at (604)-822-8598 or by email to RSIL@ORS.ubc.ca

Subject Consent:

I understand that participation is entirely voluntary. I may choose not to have samples and medical information collected from me. I may withdraw my permission to use my samples and my medical information in the future. If I withdraw this permission at any time, my samples and information in the BCCA-TTR will be destroyed. Although I cannot have access to specific test results directly related to my individual tissue samples, I may ask questions about the type of research being done. I will receive a signed copy of this consent form including all attachments, for my own records.

a. I agree to the use of tissue samples and data collected from me for research and teaching purposes related to cancer research that will involve testing my tissue sample for features of cells that may provide a better understanding of how tumors develop, grow, spread, and how tumors can be better treated.

   Yes _____ (Initials) No _____ (Initials)

b. I agree to the use of blood samples collected from me for research and teaching purposes related to cancer research that will involve testing my tissue sample for features of cells that may provide a better understanding of how tumors develop, grow, spread, and how tumors can be better treated.

   Yes _____ (Initials) No _____ (Initials)

c. I agree to be contacted in the future to discuss whether I will give permission for my samples to be used for hereditary genetic research or other types of research.

   Yes _____ (Initials) No _____ (Initials)

_____	_____	_____
Subject's Signature	Printed name	Date

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

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

Was the subject assisted during the consent process in one of ways listed below? ☐ Yes ☐ No

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

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

☐ The person signing below acted as an interpreter/translator for the subject, during the consent process (**please check if an interpreter/translator assisted during the consent process**).

_____	_____	_____
Signature of Person Assisting in the Consent Discussion	Printed name	Date