

This Patient Information Sheet is **5** pages long. Please make sure you have all the pages. If English is not your preferred language and you would like this information in another language, please ask and it will be provided or an interpreter called. You are encouraged to take this document home and discuss your decision to donate tissue for cancer research with a family member. Prior to your procedure, you will be asked to sign a Tissue Bank Consent Form. By signing this form, you indicate that you understand this information and you give consent to donate tissue as a gift to the **{Local Tissue Bank}** Tissue Bank. A copy of the Consent Form will be given to you to keep and the original will be placed in your medical record.

1) What is the Tissue Bank?

The **{Institution}** Tissue Bank is a non-profit service **aimed** at facilitating ethically sound and scientifically valid research using human tissue. It is a member of the Victorian Cancer Biobank (VCB), which is supported by the Cancer Council of Victoria, and which assists in the sharing of tissue samples between participating institutions. The Tissue Bank is located **{physical location of Tissue Bank}**. The Tissue Bank has obtained approval from **(Institution name)** Human Research Ethics Committee to collect and store blood, tissue samples and information from healthy individuals and from patients who may have cancer or who may be at risk of developing cancer (e.g., because of a family history of cancer). When a researcher decides to study *diseases and* certain types of cancer, they apply to the Tissue Bank for tissue samples. The Tissue Bank then provides samples to the researcher if the research project meets the required ethical and scientific standards. Even if you don't have cancer, excess tissue donated from your operation or biopsy could benefit medical research.

2) What do you want from me?

Scientists and doctors who study the biochemical and genetic causes of certain types of cancer to find better ways of predicting, treating or even preventing cancer need to look at blood and tissue samples from a large number of people with similar diseases. This research depends on people like you to donate, as a 'gift', blood and tissue samples for research. The Tissue Bank may only collect, store and distribute blood and tissue samples with the permission of the person who donated the tissue. Therefore, we are asking your permission to do five things: **First**, to collect **25-50ml** (about 2 ½ to 3 ½ tablespoons) of blood from a vein in your arm. This sample needs to be collected as close as possible to the time of your procedure. **Second**, to collect additional blood samples during follow-up visits to your doctor or at a laboratory near you. **Third**, *after* the tissue has been removed from your body and sent to the laboratory for diagnostic testing, we wish to take a small piece of tissue that is not needed for diagnostic testing. **Fourth**, we would like to follow your progress after your procedure by collecting information from various health agencies, your medical records or cancer registries. This clinical information adds value to the specimen you have donated. **Finally**, you may be asked to fill in a survey or a questionnaire that gives the researchers information that will help their research.

3) Isn't all of my tissue needed to make a diagnosis?

Generally, no. If there is tumour present, your surgeon will remove it and some of the surrounding normal tissue to ensure that all of the diseased tissue is removed. The specimen is sent to the pathology laboratory where a doctor examines it. This doctor, called a pathologist, selects areas of the tissue that will be processed into paraffin (wax) tissue blocks. These blocks are cut into very thin slices, mounted on glass slides then stained. The pathologist views the slide under a microscope, makes a diagnosis and then sends a report to your doctor. After the diagnosis has been made, there is usually tissue remaining in these wax blocks, which are stored or 'archived' indefinitely in the laboratory.

4) If I donate tissue how much will The Tissue Bank take?

The Tissue Bank is only given tissue that is not needed by the pathologist in making your final diagnosis. This tissue is considered to be in excess and would normally be destroyed if it were not donated to the Tissue Bank. There is no guarantee that any of your tissue will be taken for tissue banking-- that is for the pathologist to decide. If there is any tissue to be banked it may be used fresh or it will be stored frozen or preserved in wax blocks for future research studies. Usually, we receive several pieces of fresh tissue, some normal tissue and some abnormal or tumour tissue, about the size of a 5-cent

coin. If you agree to be a donor, no additional procedures will be performed unless you agree to have follow-up blood samples taken at a later date. **Bone Marrow:** If your doctor has requested a bone marrow biopsy as part of your clinical management program, we ask if you would like to donate some extra bone marrow tissue to be taken for research purposes. Only one procedure will be undertaken. The collection of extra bone marrow for research (2-10 ml) will be done at the same time as the routine diagnostic bone marrow collection.

5) Why do you need blood or bone marrow?

If you allow us to collect blood, 25 to 50ml (about 2 1/2 to 3 1/2 tablespoons) of blood it will be drawn from a vein in your arm through a needle. This is the same procedure as having an ordinary blood test, except that you will not receive a test result. We will try to ensure that the collection of blood for research will be done at the same time as blood collection for tests that you would otherwise have. The same is true if you are having a bone marrow biopsy. Your doctor will take an extra 2-10 ml of bone marrow during your procedure. Researchers may want to study the proteins and genetic material (DNA and RNA) present in your cells. Many cancers and diseases of the blood cannot yet be detected in their early stages, but scientists are working hard to develop blood tests that might alert people to such cancers while they are still in their early stages so that there is a good chance that it can be treated and cured. To develop new tests researchers need to test hundreds of blood samples from patients like you. One way to do this is to collect and compare multiple blood samples from the same patient over a long period of time. Researchers may want to study and compare the level of substances in your blood (e.g. proteins or hormones) before and after surgery. These results can be used to discover the genetic basis of diseases or determine important biomarkers that may predict disease onset, prognosis or progression. If you allow follow-up bloods to be taken, we will collect 25 to 50 ml of blood at intervals. These procedures will usually happen during your follow-up visit to see your doctor and are completely voluntary; as such you can stop follow-up collections at any time.

6) Who will use my tissue?

Researchers from within Australia or even overseas can apply to the Tissue Bank provided the project has the approval from a Human Research Ethics Committee (HREC) and the VCB Access Committee. HRECs, which are made up of doctors, lawyers, research scientists, community members and ethicists, ensure that projects are scientifically sound and are conducted according to the National Statement on Ethical Conduct in Research Involving Humans (June 1999) as issued by the National Health and Medical Research Council of Australia

7) What kinds of research will my blood and tissue be used for?

The Tissue Bank provides tissue samples to scientists who are involved in various aspects of cancer research, so we cannot say exactly what projects your tissue samples will be used for now or in the future. Some scientists may study the genetic material inside your cells while others may study the proteins produced by those cells. Regardless of the specific details of the project, your tissue samples will be used to study the causes of cancer and/or develop improved methods for the detection, diagnosis, monitoring and/or treatment of cancer. Other scientists may want to study how diseases are passed on in families by comparing the genetic material (proteins or genes) present in both normal and cancer cells within similar groups of patients; this is called genetic research.

Sometimes a researcher may want to access the paraffin tissue blocks that were used in making the diagnosis of cancer and which are stored (archived) in pathology laboratories. This occasionally happens when the Tissue Bank does not have sufficient material of its own to give to the researcher. We can obtain access to these archives only if we have your permission and that of the Pathology Department.

Cells obtained from your blood or tissue may also be used to establish cell lines. A cell line consists of cells cultured to grow for a very long time in the laboratory. Cell lines, therefore, allow the creation of a large supply of material for research. This allows material to be shared with other research groups and enables researchers to compare each other's results. Only researchers who have special approval can establish cell lines or perform genetic research.

Rapid advances in technology make it impossible to predict what new tests or studies may be possible in the future. Therefore, when a researcher wishes to use your tissue for future research, a Human Research Ethics Committee will decide if the research can proceed.

8) Will my tissue ever be sold to some company for profit?

The (Institution name) Tissue Bank is a non-profit service dedicated to providing a resource to scientists involved in medical research. Your tissues may be provided to approve researchers from such areas as hospitals, universities, medical research institutes, government affiliated institutions and commercial organizations such as pharmaceutical companies. Your tissue will NOT be sold. The Tissue Bank may charge researchers a fee to recover some of the costs of storing and administering its collection of tissue, but tissue is never sold. Also, although knowledge acquired through medical research may lead to discoveries that are of commercial value to the researcher and their institution, there will be no financial benefit to yourself, your family or the Tissue Bank

9) Will I find out the results of the research using my tissue?

You have the legal right to access your medical records at any time. In the course of your medical care you will receive the results of your procedure from your doctor. This information is a part of your permanent medical record, but you will not receive specific research results. This is because research by its very nature, is experimental, can take many years and uses samples and data from a large number of people, so what a researcher discovers in this context may be of little value to you, your family or your future health.

10) What if research discovers something of medical importance to me or my family?

The vast majority of research projects for which your tissue might be used are unlikely to reveal anything of medical importance specifically for you or your family. However, if that should happen and a discovery is made that predicts a possible medical condition, the researcher is required to inform the appropriate Human Research Ethics Committee and the Tissue Bank. The committee will examine the research data and decide whether or not it may be in your interests for you to be contacted. If this knowledge is of medical significance to you and/or your family the Tissue Bank will contact your doctor and you will be given the option of learning more information at the time. If we are unable to contact your doctor, we will make a reasonable attempt to contact you at your address provided or any updated address that you might care to provide.

11) What are the risks and benefits of tissue donation possible genetic testing?

Genetic research involves the study of genetic material (DNA), which is shared with your blood relatives. Genetic research raises many important issues. It is unlikely that these issues will arise, but you should think about them carefully. Genetic research is undertaken to discover more accurate ways of predicting diseases within a group of people or in people where there is a strong family history or predisposition of disease. To perform such studies, a researcher must demonstrate to a Human Research Ethics Committee that procedures are in place to provide genetic counseling if required.

The Benefits:

As to donating your tissue, it is unlikely that there will be a direct benefit to you or your family. We plan to store your tissue samples for a very long time. Your sample may not be used for many years until a new and as yet undiscovered approach to study cancer is developed. Therefore, the benefit may not be to you but to future generations of cancer patients.

Genetic research could provide a means of identifying people within a family with an increased risk of developing a disease for which there is a recognized treatment or possible cure.

This research may also allow an individual and their family to take steps to prevent a disease before it occurs, e.g. by having screening tests, if they are available, and, if necessary, by making lifestyle changes.

The Risks:

The tissue we collect is obtained after it has been removed from your body and would normally be destroyed, so there is no physical risk to you. If blood is taken you may feel a slight pinch in your arm when the blood is drawn and you could develop a small bruise. If an additional bone marrow sample is taken, it can sometimes cause discomfort or pain at the site of the aspiration. This usually lasts about 30 seconds. After the diagnostic procedure is over there may be some soreness that can last 2-3 days. If you choose to answer a patient survey, it is possible that answering the questions could be upsetting, if, for instance, the survey arrives at a time when you are not feeling well or you are feeling anxious. Of course, you may decline to participate in a survey or answer a specific question in the survey.

Learning the results from genetic research might create uncertainty or be upsetting; if for instance, the risk of developing a disease is identified which has no known prevention, treatment or cure.

Some people may learn disturbing information about inherited diseases or a disorder involving their children, brothers or sisters. This could interfere with family relationships. You may be faced with the question of “should I tell the family?” Other family members may or may not wish to know this information. It is important to understand that results from genetic research usually will not indicate that you have a disease or disorder, or whether you will develop it. Research may only show that you have an increased risk of developing a disease or disorder. Even then, there is no guarantee that you will develop the condition.

Any research results that could be of significance to you or your family will need to be repeated and verified. This may involve having a blood sample taken and having it retested in an accredited testing laboratory. This is standard practice for all patients receiving the results of genetic testing and would be provided free of charge to you. Counselling may also be provided free of charge if it is appropriate. Before a test is repeated to verify a research finding you will be informed about the possible risks involved. This is especially important for individuals who are found to have a gene mutation, which increases their risk of disease or cancer. Knowing such information could lead to job discrimination and difficulties in obtaining some forms of insurance.

On the Consent Form you will be given the option of having your sample excluded from studies that identify genes or diseases that run in families e.g. diseases that can be passed on (through DNA) to blood relatives. If you wish your samples not to be used in such studies, please tick the “NO” box next to Question 4 on the Consent Form. Whatever choice you make, your privacy will be protected and your decision will be respected.

12) What other types of information do we want?

The Tissue Bank would like to collect information from your medical record, such as your height, weight and blood pressure before your procedure and record the details of your condition, such as the diagnosis and the results of various tests. We would also like to follow your progress after your procedure by looking at information that your doctor has collected from you during your routine follow-up visits. You will not have to make a special trip or appointment for this. Your doctor may record such information as the medications that you are taking and whether your appetite has changed. We would also like your permission to send you ethically approved surveys or questionnaires to complete. This enables us to collect standardized information from large numbers of tissue donors. They ask questions about lifestyle choices such as ‘do you smoke?’ or ‘do you exercise?’ We would also like to obtain and/or verify your details from information stored at various health agencies, or cancer registries. No personal information will be collected without your permission.

13) How is my privacy protected?

Personal information, such as health information will remain privileged and confidential, except as required by law. Although information collected by the Tissue Bank about you will be identifiable (i.e. information will be linked to your name or hospital medical record number), the Tissue Bank is required to keep this information secure and confidential in order to protect your privacy. Identifiable information about you will not be given to anyone without your written consent. Information provided to researchers is de-identified, meaning that personal information, such as your name or date of birth are removed and replaced with a unique code known only to authorized Tissue Bank staff. Tissue and data supplied to researchers are coded in this way to ensure that nothing that can identify you or your family will ever appear in any published report or journal. To ensure that these policies are followed, the Tissue Bank is audited and the **(Institution name)** Human Research Ethics Committee monitors all research projects they approve. This is usually done annually, by requesting a report from the Chief Investigator for the research project. This report covers matters such as the maintenance and security of records and compliance with the project as originally approved by the HREC.

14) What becomes of my tissue if I die?

In the event of your death, we will continue to store your tissue samples and make them available for use by researchers. Your gift will continue to be used in cancer and other bio-medical research subject to the same legal and ethical standards discussed in this document. On the Consent Form you may nominate a representative to be contacted about any matters that

we would have contacted you about. This person should be a blood relative or spouse/partner. Please discuss the possible implications of your donation with whomever you choose as your representative.

15) What if I do not wish to donate tissue?

No matter what you decide to do about donating your tissue, it will not affect your care now or in the future. You are under no obligation to donate blood or tissue. The tissue removed during your procedure that is not needed for diagnosis will be destroyed in the usual manner.

16) What if I change my mind?

Your participation is completely voluntary. You can change your mind and withdraw your consent at any time, and it will not affect your medical care. If you wish to withdraw your consent, simply contact a representative of the **(Institution)** Tissue Bank and they will send you a Withdrawal of Consent Form. If any of your tissue samples are still in storage, they will be destroyed.

17) Who can I contact if I have more questions?

The (Institution) Tissue Bank is open during usual working hours. If you have any technical questions about the way your samples are being handled or you require further information about the types of information that are routinely collected or about the research project(s) your tissue is/are being used for, you may contact the Tissue Bank Manager on **(phone number)** Tissue Bank Manager on (phone number). The Principal Investigator of the Tissue Bank, **(title, name and phone number)**.

18) Who can I contact who is independent of The Tissue Bank?

The Human Research Ethics Committee of (Institution) has approved the operation of the Tissue Bank. This is to ensure that the required ethical standards are met and that the confidentiality of participants is protected. If you have any concerns or complaints about the Tissue Bank, these should be directed to the **(Site specific name: ethics coordinator/manager and phone number: Name Patient advocate and phone number)**.

Protocol Number: Title: Project Coordinator: Associate Coordinators: Institution:	
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