

PARENT/GUARDIAN or PARTICIPANT INFORMATION SHEET

Investigators:

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This information sheet has been written to help you decide whether you would like to donate your/your child's samples to the Tumour Bank at this hospital. You are being asked to read this information sheet because you/your child had tests done at this hospital and we would like to use some of your/your child's left-over test samples for research.

1) What is a Tumour Bank?

A tumour Bank is a valuable resource aimed at supporting research into cancer. It provides cancer researchers (who have appropriate regulatory approval) with tumour tissue and other biological specimens along with important clinical information about the specimen.

The Tumour Bank at The Children's Hospital at Westmead focuses only on childhood cancer research. It has appropriate approvals from the Sydney Children's Hospitals Network Human Research Ethics Committee to collect, store and distribute tissue, blood, bone marrow, urine, saliva samples and relevant clinical information of patients who may have cancer. The Tumour Bank provides these samples to a researcher if their project has ethical and scientific approvals. The Tumour Bank is a not-for-profit service funded by the NSW Government, National Health & Medical Research Council of Australia, Cancer Institute NSW and The Kids Cancer Project.

2) Why am I being asked to donate leftover tumour, blood or bone marrow?

Donating your or your child's biological samples to cancer research will help increase knowledge of cancer and help to answer important questions about cancer, such as how to predict who might be at risk of getting cancer, how to find new and more effective drugs to treat cancer and ultimately cure it and how to prevent cancer. Scientists need real human cancer tissue to learn how cancer behaves as the disease progresses through the body; how cancer tissue compares to a normal tissue and what genes and processes are involved in making normal cells become cancerous and spread. Only then can new drugs and therapies and new diagnostic tests be developed so the cancer can be detected earlier and treated with fewer side effects. Even if a patient doesn't have cancer, leftover tissue donated from an operation, biopsy or pathology test could benefit cancer research.

The Tumour Bank has a legal and ethical responsibility to ask for your permission to use your or your child's tissue in medical research and to provide you with all the information you need to make your decision about whether you and/or your child would like to become a donor.

3) Will participation involve extra needles and procedures?

No. The Tumour Bank collects and stores left-over tumour, bone marrow, blood and other biological samples that were collected during routine medical procedures. Extra blood, urine, bone marrow or other biological specimens would only be collected when routine tests are ordered by your/your child's doctor, so this will not involve extra needles, biopsies and procedures for Tumour Bank collections.

4) What happens if I agree to donate tissue?

Scientists and doctors who study cancer need to look at blood and tissue samples from a large number of people with similar diseases to make decisions about possible future treatments and directions for research.

We are asking your permission for the following:

- Store any leftover blood from your/your child's routine and follow-up tests. We are most interested in samples collected at initial diagnosis, at a relapse episode and at specific treatment intervals for leukaemia patients.
- If there is insufficient leftover blood available, we would like to collect blood from a vein in your/your child's arm at their next routine test for diagnoses and treatment (an extra 4-9mL - about 1 to 2 tablespoons). This would not involve an additional needle.
- If you/ your child undergo a bone marrow biopsy for diagnosis or routine management of your/your child's illness, we request the collection of extra bone marrow for research at that time. This means an extra 4-9ml (about 1 to 2 tablespoons) of bone marrow. Bone marrow biopsy is a procedure done under general sedation.
- When the tumour tissue has been removed from your/your child's body and sent to the laboratory for diagnostic testing, we request that any tumour tissue that isn't needed for diagnostic testing be sent to the Tumour Bank.
- From time to time we would also like to store other leftover tissue and samples, for example urine, saliva samples or other biological samples that were collected as part of your/your child's diagnosis and routine investigations.
- We would like to record your/your child's progress after the procedure by collecting information from your/your child's medical records or cancer registries. This clinical information adds value to the specimen you have donated.

5) Isn't all of the tumour, blood or biological sample taken needed to make a diagnosis?

At the time of surgery, the surgeon aims to remove the entire tumour and some of the surrounding normal tissue to make sure that all of the diseased tissue is removed. The tissue specimen is sent to the pathology department where a pathologist selects areas of the tissue that will be processed. This allows the pathologist to examine the sample and make a diagnosis for your doctor. After the diagnosis has been made, these processed pathology samples are stored or "archived" indefinitely in the laboratory. Remainder of the tissue is of little use to the pathologist and may be given to the Tumour Bank or thrown out.

Blood is often taken to complete all the tests ordered by your/your child's doctor. Usually there is some blood leftover from this sample that hasn't been used by a pathology lab and will be thrown out, generally after 7 days of your blood test.

6) If I/my child donate tumour/tissue how much will the Tumour Bank take?

The Tumour Bank is only given tissue that is not needed by the pathologist in making your/your child's final diagnosis. This tissue is considered to be leftover and would normally be destroyed if it were not donated to the Tumour Bank. There is also no guarantee that any of your/your child's tissue will be taken for tumour banking – that is dependent on the quantity available for the pathologist and so, the amount that goes to the Tumour Bank is for the pathologist to decide. Whether Tumour bank will store this tissue or not is based on your consent.

7) Why do researchers need blood or bone marrow?

Researchers may want to study the proteins and genetic material (DNA and RNA) present in your/your child's cells. If you/your child are diagnosed with a solid tumour, DNA in your/your child's blood cells would be considered normal in comparison to DNA in the tumour cells. Scientists will use the blood and compare this to the tumour.

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 they can be detected early for early treatment and cure. To develop new tests researchers need to test hundreds of blood samples from patients like you/your child. Researchers are also interested in the progression and treatment of a disease. To understand how the treatment is working, many blood samples from the same patient over a long period of time may be needed. Researchers may want to study and compare the level of substances in your/your child blood (for example, 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.

8) What other types of information would the Tumour Bank like to collect?

The Tumour Bank would like to collect medical information from your/your child's medical record before your/your child's procedure and record the details of your/your child's condition, such as the diagnosis and the results of various tests. We would also like to follow progress after a procedure by looking at information that your/your child's doctor has collected from you and /or your child during routine follow-up visits.

9) How will my/my child's privacy be protected?

Personal and health information collected by the Tumour Bank from your/ your child's medical records is treated with the utmost importance to remain confidential. Information is stored on a secure database and a secure area which can only be accessed by authorised Tumour Bank staff. Your/your child's tissue, blood, bone marrow or any other biological sample will be given a unique code. Only the Tumour Bank staff will be able to link that code back to your/your child's personal and health information. Researchers will receive de-identified samples - samples that have only the unique code and the clinical information relevant to their research. This is to protect your/your child's privacy and to make sure that nothing that is distributed to researchers can identify you or your family.

10) What if I do not wish to donate my/my child's tissue or blood?

The decision to donate to the Tumour Bank is voluntary and it is up to you and your family whether you decide to donate or not. It will not affect your/your child's care in this hospital now or in the future. If you decide not to allow samples to be kept by the Tumour Bank, the leftover biological samples removed during your/your child's tests or procedures and are no longer needed for diagnosis or treatment decisions will be destroyed according to The Children's Hospital at Westmead waste management policy.

11) What if I change my mind?

If you decide to allow the Tumour Bank to retain samples, but later change your mind, that is OK. You have the right to change your mind and withdraw your consent at any time, without giving any reasons. Simply contact the Tumour Bank and state your request to withdraw consent. If any of your samples are still in storage, they will be destroyed. However, samples that have already been supplied and used in a research project will not be able to be retrieved.

12) Who will use my/my child's tumour, blood or bone marrow sample?

Researchers from Australia and overseas apply to The Tumour Bank to access these samples for important cancer research. The Tumour Bank will only provide the sample to credentialed cancer researchers with projects approved by an authorised Human Research Ethics Committee which is made up of doctors, lawyers, research scientists, community members and ethicists to ensure that projects are ethically and scientifically appropriate. The research project is also reviewed by the Tumour Bank Committee to make sure the research is worthwhile and samples are used appropriately.

13) What particular research project will my/my child's samples be used for?

Samples collected and stored by the Tumour Bank are not meant for one particular study or a project. That is why we cannot give you the specific details of the research study that your/your child's tumour, blood, bone marrow or other samples will be used for. Scientists may study DNA of cancer cells or proteins and other molecules affecting growth of tumours and how different doses of chemotherapy drugs affect them. There is a chance your/your child's samples may be used in genetic research which is aimed to study risk of predisposition to cancer in people with strong family history of cancer or within a group of people. Regardless of the specific details of the research project that receives your/your child's tissue samples, it is certain that the sample will be used to study cancer. Fast developments in technology make it impossible to predict what new tests or studies may be possible in the future, this is why we are requesting your approval to use your/your child's samples for any authorised unspecified research. All research must be reviewed and approved by a Human Research Ethics Committee prior to receiving any Tumour Bank samples.

14) Will I be notified of the results of a research project where my /my child's samples were used?

You will not receive specific research results. A research project can take many years and uses samples and data from a large number of people. Of course, if a research discovery could directly benefit you/your child or your family, the researcher will contact the Tumour Bank, and the Tumour Bank will contact your doctor so that you can be notified as needed.

In the event that incidental/unexpected information relevant or useful to you, your child or your community becomes available, the researchers who have been given your child's sample have agreed to provide the results to the Head of the Tumour Bank or the Steering Committee that governs the Tumour Bank. If information becomes available, you and your child will be informed of this information by your treating doctor or GP who is listed on your medical records charts. You can choose to be notified of these findings by ticking the correct box on the consent form.

15) Will my/my child's tissue ever be sold to any company for profit?

Your tissue will NEVER be sold. The Tumour Bank is a not-for-profit organisation and may charge researchers a fee to recover some of the costs of storing and administering its collection of tissue, but tissue is never sold.

16) If my/my child's sample leads to a financial benefit to the researcher or their institution, will I/my child be able to benefit too?

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 Tumour Bank.

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

You can contact the Tumour Bank at any time Monday to Friday between 9am and 5pm:
A/Prof Daniel Catchpoole, Head of Tumour Bank, Ph: (02) 9845 1205
Ms Oksana Markovych, Clinical Research Associate, Ph: (02) 9845 1214

18) Who can be contacted independent of the Tumour Bank?

If you have any concerns or complaints about the conduct of the Tumour Bank, these should be directed to:

Sydney Children's Hospital Network Human Research Ethics Committee
Research Ethics Executive Officer, Ph: (02) 9845 3066

Or Sydney Children's Hospital Network Research Governance Office, Ph: (02) 9845 3011

Thank you for taking your time to consider tissue donation to the Tumour Bank.

If you wish to proceed, please sign and return the attached consent form.

The information sheet and a copy of the consent form are for you to keep.