Information statement and consent form

HREC Project Number: 33207

Research Project Title: **The Children's Cancer Centre Biobank**

Principal Researcher: Professor Rachel Conyers, Children's Cancer Centre

Version Number: 19 **Version Date:** 13 October 2025

Thank you for taking the time to read this **information statement and consent form**. We would like to invite you to participate in The Children's Cancer Centre (CCC) Biobank which is explained below. This document is 6 pages long. Please make sure you have all the pages.

It is up to you whether you take part. You can say no if you want to. Your medical care will be the same whether you join the Biobank or not. You can ask us questions before you make a decision. You may want to talk to your family, friends or health care worker before making a decision. If you agree to participate, please sign the consent form at the end of this information statement.

When we say "you", we mean you or your child. If you are a parent or legal guardian of a child aged less than 18 years old, your permission is required. If your child is giving their samples and health information to the Biobank, make sure you tell them about this when they turn 18. We will keep using their samples and information after they turn 18 unless they tell us not to. They can withdraw their consent once they turn 18 as outlined in Section 5.

Please scan this QR code for a video introduction to the Biobank.

1. What is the CCC Biobank?

The Biobank is a valuable collection of biological samples such as tissue collected during surgery, blood and bone marrow. These samples are linked to health information contained in hospital medical records. Health information used may include age, gender and information about test results and medical care.

Samples and health information in the Biobank are given to scientists in Australia and around the world. Researchers rely on these types of samples and health information to make research discoveries and medical breakthroughs. They hope to find new ways to better prevent, detect and treat different conditions. Our Biobank includes samples and health information from people with cancer, bone marrow disorders, primary immunodeficiency disease, neurofibromatosis and giant melanocytic naevi. It also includes samples and health information from their siblings, parents and relatives.

We are asking for your consent to donate your samples and use your health information for research. This information statement will help you make an informed decision about taking part in the Biobank and will cover:

- How your samples and health information will be collected and stored
- How your samples and health information will be used
- How the Biobank protects your privacy and confidentiality
- And finally, the potential risks and benefits if you decide to participate

2. Who is funding and managing the CCC Biobank?

The Biobank is funded by CIKA (Cancer In Kids @ RCH, http://www.cika.org.au/) and The Royal Children's Hospital Foundation. The remainder of funds and in-kind support are provided by The Royal Children's Hospital (RCH) and Murdoch Children's Research Institute (MCRI). The Biobank is managed by a team with the responsibility of ensuring the samples and associated health information are kept secure. They also need to make sure that samples are only used in research projects approved by a Human Research Ethics Committee.

3. Why am I being asked to participate in the CCC Biobank?

We are asking you because you are a patient at the Melbourne Children's campus which includes The RCH, MCRI and the University of Melbourne Department of Paediatrics. These organisations can share research information with each other.

4. What does participation in the CCC Biobank involve?

You need to have some procedures and tests as part of your medical care. This may involve collecting samples, such as tissue collected during surgery, blood, bone marrow or fluid such as cerebro spinal fluid. This is routinely done to help diagnosis prior to treatment, during the course of treatment to monitor progress, or after treatment to determine an outcome.

We are asking for your consent to all of the following parts:

1. Store and use any samples **leftover** from your medical care. These include samples such as tissue collected during surgery, blood, bone marrow or fluid. You will not need to get any extra tests. In most cases we will simply use your samples that are leftover from the tests you need to get as part of your medical care.

2. Collect, store and use a small amount of **extra blood** at different stages of care. This means that when you give a blood sample as part of your medical care, we will collect a bit extra for the Biobank. We ask you to give about 1-3 teaspoons of extra blood. We will simply collect extra blood when you are giving blood as part of your medical care.

3. Collect, store and use a small amount of **extra bone marrow and/or cerebro spinal fluid.** This means that when you give these samples as part of your medical care, we will collect a bit extra for the Biobank. We may ask you to do this up to six times. You will not need to get any extra needles. We will simply collect extra samples when you are getting a procedure as part of your medical care.

4. Use stored **blood-derived products** which are not needed for treatment. Your medical care may involve your blood undergoing a process called apheresis that collects specific blood components needed for your medical care. We ask to use these blood-derived products if they are not needed for your medical care.

5. Collect, store and use a **saliva sample** including the cells and genetic material (DNA) it contains. Our bodies are made up of different types of cells. Inside each cell is the genetic material packaged as pairs of genes. A gene is like a small microchip. It contains information and sends messages that help shape us. For example, genes can shape our eye colour and blood type. Genes are arranged along a chemical substance called DNA. DNA can be used for genetic research.

This is an additional sample for the Biobank. We will ask you to give this saliva sample at a convenient time when you are coming to the hospital for an appointment or we may mail a saliva collection device which can be returned in a pre-paid envelope.

6. **Create, store and use a cell line and an induced pluripotent stem cell (iPSC) line**. Samples that we have already collected such as blood or tissue will be used to establish a cell line or a special stem cell line called an induced pluripotent stem cell (iPSC) line.

   This means that we will use cells from different types of tissue or blood and grow them in the laboratory. This will allow us to produce a continuous supply of cells for research. Some cell lines will only grow for a limited amount of time while others may become 'immortal' and grow forever. Creating cell lines often involves growing human cells in other species such as mice so the cells can grow. Human cells grown in other species are called "xenografts". These cell lines are used to discover how diseases develop and to test new medicines before testing in patients.

   Creating an iPSC line uses technology which allows cells to be reprogramed to stem cells which can then be turned into many different cell types. This means that we can study the specific type of cell that is not working properly in an affected individual. These cells give researchers more information about how cells work to discover how disease develops, giving us clues on how to prevent or reverse it.

7. **Access and use tissue blocks**. After your surgery tissue was sent to Anatomical Pathology at The RCH and a tissue block was created. The tissue was put into paraffin which keeps it in a way that we can look at it again in the future. These tissue blocks were used in making your diagnosis. The Biobank will access these tissue blocks which were used in making your diagnosis and tissue blocks from other surgeries you have had in the past or will have. Anatomical Pathology will make sure your tissue block will only be used in the Biobank if there is more than is needed to be kept for future testing.

8. **Access your hospital medical records.** We will use your health information contained in your medical records after removing any information that can identify you (such as your name, address or date of birth). Health information used may include age, month and year of birth, gender, family health history, information including test results, medical procedures, images (such as scans) and medicine you take. We will access your hospital medical records to update your health information on a regular basis.

If you say yes to taking part, we would also like you to consider agreeing to some additional options. These are giving us access to your Newborn Screening card and letting us collect and use a skin sample from you. These are optional, you can say no to one or both if you want to. If you say no to one or both of them, you can still participate in the rest of the project.

Optional consent to access and use your Newborn Screening card.
If you were born in Victoria we request your consent to access your Newborn Screening card stored at the Victorian Clinical Genetic Services (VCGS). All newborn Victorian babies have a heel prick blood test taken in the first few days of life to test for serious and treatable conditions. The remaining spots of blood after testing are stored as a Newborn Screening card at VCGS. Each Newborn Screening card usually has four dried blood spots and we request access to a single dried blood spot. VCGS will make sure they keep one complete blood spot in storage should it be needed for future medical reasons.

Optional consent to collect and use a skin sample.
We are asking you to let us collect a small piece of skin (3mm) for the Biobank. This will serve as a healthy tissue sample because your blood and saliva may contain cells that are not normal. In most cases we will collect the skin at the same time that you are having another test under anaesthetic to minimise discomfort. For example, we may collect skin from near the hip when your bone marrow test is performed or at the place where a central venous line is inserted. In rare cases, we will collect skin from an area such as your inner upper arm or abdomen, this will require local anaesthesia. This is an additional procedure and your doctor will discuss this with you.

Please tick the appropriate box on the consent form to let us know if you consent to one or both options.

We may need to collect extra samples before asking you, we will only use the samples if we have your consent. If you need samples for your medical care, we will not use them in the Biobank. We will only use any samples that you do not need.

If you are thought to have a condition but found that you do not, your samples will still be stored and used in the Biobank. If normal samples are collected during your surgery as part of your medical care, these samples will also be stored and used. Tonsils will be collected, stored and used from patients undergoing a tonsillectomy procedure. These types of control samples are valuable for comparison to samples that contain disease.

We will give samples and health information in the Biobank to scientists at the Melbourne Children's Campus and to researchers at other sites in Australia and overseas. Your samples and health information may be provided to sites such as hospitals, universities, medical research institutes, government affiliated institutions and commercial organisations such as pharmaceutical companies. We hope that this will help them make research discoveries and medical breakthroughs that can find new ways to better prevent, detect and treat different conditions. If researchers want to use samples and health information from the Biobank, they will have to undergo lots of checks. This includes scientific review as part of the CCC Biobank Access and Oversight Committee. Also an ethical review by a Human Research Ethics Committee.

5. Can I withdraw from the CCC Biobank in future?

At any time, you can ask the Biobank to destroy samples and health information that are stored with us. But we will not be able to destroy any samples and health information that have already been used or shared with researchers. If you want to withdraw your samples and health information, please contact the CCC Biobank. Their details are on page 5.

6. What are the possible benefits for me and other people in the future?

Participating in the Biobank may not directly help you. However, it will help researchers in Australia and around the world understand more about different diseases and how to detect, prevent and treat them. Choosing to participate in the Biobank will help researchers make a difference to medical research and to the health of future generations.

If you happen to join a clinical trial, we can use the samples in the Biobank for the clinical trial. This way we will not need to collect extra samples.

Your samples and health information will never be sold. The Biobank may charge researchers a fee to recover some of the costs of administering its collection of samples. You should be aware that knowledge acquired through medical research may lead to discoveries that are of commercial value to the researcher and their site. You will not receive money or other forms of payment for use of samples and health information.

7. What are the possible risks, side-effects, discomforts and/or inconveniences?

There will not be any increased risk in taking the samples as these samples will be collected at the same time as samples that are part of your medical care.

Samples may be used for genetic research which involves testing and studying genetic material, usually DNA. Genetics is the study of genes and how certain traits or conditions are passed down from one generation to another. Many health conditions or diseases are caused by a change in one or more genes. These conditions may emerge at birth or may appear later in life. However, sometimes a gene can change without causing a health problem. If the Biobank gets told about a change in your genes that might be an important risk factor for disease, you will be contacted by your doctor or a genetic counsellor to discuss this with you. This could happen many years after your sample was collected. If you don't want this to happen you should not participate in the Biobank.

You may experience bleeding and/or bruising where the skin sample is collected. The piece of skin is very small so the area is likely to heal quickly, and only a small scar will form. In rare cases you may get an infection.

8. What will be done to make sure my information is kept confidential?

Your samples and health information will be safely stored in a highly secure laboratory and office area at MCRI. The samples will be safely preserved for many years or until a researcher requests them. There is no time limit as to how long your samples and health information may be stored in the Biobank.

Your name and other identifying information are removed from your samples and replaced with a unique code. Only staff at the Biobank can use this code to your identifying information. When we share your samples and health information with other researchers, we use this code so they will not know who you are. The results of any research that is published and presented will be done in a way that you cannot be identified.

The following people may access your samples and health information in the Biobank:

- the CCC Biobank and team members who are all from the Melbourne Children's, for the development, operation, use and maintenance of the Biobank
- The RCH Human Research Ethics Committee for monitoring purposes

Your privacy is important to us. We will make every effort to protect it. MCRI complies with the *Australian Privacy Act 1988* (Cth) and other applicable Australian and/or Victorian privacy laws and protects your information in accordance with our Privacy Policy available at www.mcri.edu.au/privacy-policy. In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about you. Please read our Privacy Policy for more information about how you may access and correct your personal information, how to complain about a breach of the Privacy Act and how MCRI will deal with such a complaint.

We may send samples and information to overseas laboratories for ethically approved research. These samples will not be protected by Australian laws and regulations.

Researchers have to enter into a Material Transfer Agreement with MCRI. This contract makes sure they use the samples and information properly for their own research purposes.

9. Will I be informed of the results of any research done using my samples and health information?

We will not be able to share the results of research directly with you, but we do have a website that describes research using samples and health information from the Biobank:
www.mcri.edu.au/research/projects/childrens-cancer-centre-biobank

We may contact you in future about optional research projects that you may be interested in.

If you would like more information about the Biobank or if you need to speak to a member of the research team please contact:
Name: Dr Louise Ludlow, CCC Biobank
Contact Telephone Number: (03) 9936 6048

You can contact the Director of Research Operations at The Royal Children's Hospital Melbourne if you:

- have any concerns or complaints about the project
- are worried about your rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.

Consent form

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- I have read, or had read to me in my first language, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my involvement in this project.
- I voluntarily consent to take part in the CCC Biobank and understand that I am free to withdraw at any time as outlined in Section 5.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by The RCH Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) including all updates.
- I understand I will receive a copy of this information statement and consent form.
- I agree that it is my responsibility to make sure my child is aware of their participation in the CCC Biobank.

OPTIONAL CONSENT

☐ I do	☐ I do not	☐ Not applicable	Consent to use my **Newborn Screening card**
☐ I do	☐ I do not	☐ Not applicable	Consent to the collection of a **skin sample**

Parent/Guardian Name	Parent/Guardian Signature	Date
Participant Name	Participant Signature	Date

(Only applicable if the participant has the maturity & competence to read and understand this document)

I have explained the project to the parent/guardian/participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

CCC Team Member Name	CCC Team Member Signature	Date

Note: All parties signing the Consent Form must date their own signature.