



## PARENT/GUARDIAN INFORMATION SHEET AND CONSENT FORM

**Title: Patient Responses to Leukaemia Treatment: Minimal Residual Disease Testing and Research**

**National leaders:** Dr Rosemary Sutton and Dr Toby Trahair

**Local Hospital Lead Clinicians:** Dr Toby Trahair

### WHAT IS THIS INFORMATION/CONSENT FORM ABOUT?

Your child's hospital doctor has requested that the Children's Cancer Institute performs some tests to measure minimal residual disease (MRD) for your child or adolescent. MRD test results are important for making decisions about your child's future treatment. This is because the level of residual disease (MRD) at each stage provides an early indication of whether a treatment is working properly. As well as being of benefit to your child, their MRD results combined with information on your child's progress and/or research on their leftover samples, could help children or adults who are diagnosed with leukaemia in the future.

This information sheet is designed to help you to decide if you agree to have MRD testing for your child. It also provides information so you can decide if you wish to be a part of our research, aimed at benefiting children in the future, through three different ways. You may agree to have your child's MRD test results and information on a leukaemia registry and/or agree to storage and future use of your child's leftover samples. For either of these options you may agree to us receiving future updates on your child's progress.

There is a separate section explaining each of these options.

#### 1) WHAT IS MRD TESTING?

There are a few different types of MRD testing. The Children's Cancer Institute has one of 60 laboratories worldwide that specialise in MRD testing based on the identification of features known as genetic markers that are only present in leukaemic or lymphoma cells but not in normal cells. Every leukaemia has different markers, so each child has their own test(s). MRD testing is usually done on bone marrow samples but occasionally doctors request that blood or other tissues be tested. Once markers have been identified for a patient, the residual disease (MRD) can be measured in a sample collected after treatment to see how effectively the treatment is working.

The MRD tests measure how quickly a person with acute leukaemia is responding to different treatments. MRD testing is used mainly to identify patients at higher or lower risk of relapse. We will not provide any test results to you directly. The results of MRD testing will be sent to your child's doctor, and clinical trial centres if applicable, and your child's doctor has the responsibility for interpreting these results for you. **If you have questions at any time about MRD testing, your child's hospital doctor will be happy to answer them.**

Your child's MRD test(s) will be specific for their leukaemia, so we need to keep records for any future requests for MRD testing. We will record your child's name, date of birth, diagnosis, hospital, medical record number, any clinical trial, their hospital consultant and keep a copy of the consent form in a database at the Children's Cancer Institute. We will also record your child's samples, results of leukaemia marker testing, DNA sequences, custom-made primers, best test conditions and MRD results. Access to this information will always be restricted to a few Children's Cancer Institute staff who enter the information or who need to use it by password protection.

Patient's Name (Family, Given):  
MRN:  
MRD STUDY NUMBER:



## 2) WHAT IS THE LEUKAEMIA REGISTRY?

The Leukaemia Registry will record MRD and clinical responses to therapy for patients treated in Australia and New Zealand for different acute leukaemia's – acute lymphoblastic leukaemia (ALL), acute myeloid leukaemia (AML), mixed lineage (MLL) or mixed phenotype leukaemia (MPAL) for research into ALL subtype, toxicities and treatment response. It will be a valuable source of information for our research on identifying children at higher risk of treatment failure or toxicity. We would like your permission to include your child's MRD results and to collect and include other information from their hospital doctor in the registry. The registry will not include confidential information. It would include your child's age, gender, any known high risk factors, biological and genetic features of their leukaemia, MRD results, information on their treatments and their clinical responses to treatment. The registry information will be used by scientists and doctors who want to assess the effectiveness of different new treatments for acute leukaemia in different types of patients.

## 3) WHAT ABOUT RESEARCH ON MY CHILD'S LEFTOVER MRD SAMPLES?

After your child's MRD testing is finished, some of the two or more samples may be left over. We would like your permission to store any leftover samples, including DNA or cells, for future research. They will be frozen in our Tissue Bank at the Lowy Cancer Research Centre, UNSW, Randwick, NSW, 2031 for an unknown amount of time. They will be available for medical research that has been approved by a Human Research Ethics Committee and the Sydney Children's Tumour Bank Network Committee.

Your child's samples will not be sold and will only be used for:

- 1) Tests that your child's doctor requests including MRD testing
- 2) Quality control tests to make sure our laboratory MRD test results are accurate
- 3) Future ethically approved research projects

The choice to let us keep your child's samples for future research is up to you. If you agree to let us keep leftover samples, you may change your mind at any time and we will destroy any remaining samples.

## 4) HOW WILL MY CHILD'S PRIVACY BE PROTECTED IN THE RESARCH ACTIVITIES?

**The Leukaemia registry will not include confidential information** such as your child's name, date of birth or other personal information. Their records will be identified instead by an MRD number known to your doctor and clinical trial or other registry numbers if applicable. If you give consent for your child's information to be on the registry, then the main benefit would be for future patients. Any leftover samples banked for research are identified by tissue bank patient and sample numbers and researchers cannot access personal information like names. We expect that the results of our research will be published to benefit other patients, but your child will not be identified by name.

## 5) WILL MY CHILD OR FAMILY BENEFIT FROM THE RESEARCH?

Most research will not show results for a considerable period and it is unlikely there will be any direct medical value to your child. You will not receive money or other forms of compensation for your child's samples, even if the research leads to the development of new medical products or treatments. In case the research uncovers incidental or unexpected information relevant or useful to you, your child or your community, any researchers who have been given samples have agreed to provide the results to the Sydney Children's Tumour Bank Network Committee. You can choose to be notified about any unexpected findings by ticking the option on the consent form. Then if information becomes available, you and your child can be informed of this information by your treating doctor or GP who is listed on your child's medical records charts.

Patient's Name (*Family, Given*):  
MRN:  
**MRD STUDY NUMBER:**



## 6) HOW IS THE INFORMATION FOR RESEARCH KEPT CURRENT?

Researchers who use the MRD registry information or who use your child's leftover samples may ask for up-to-date information on your child's health. If you give consent, then Children's Cancer Institute staff from the MRD group or Tissue Bank may request your child's hospital doctor or clinical trial co-ordinator or another registry for this information. Only authorised staff will have access to your child's name and other personal details. Your child's health information will be recorded using MRD, trial or registry numbers to preserve your child's privacy. In rare cases, more information may be needed from you about your child for a research project, but this will only happen if you have given specific consent.

**If you have specific questions about the Tissue Bank at the Children's Cancer Institute, you may contact Ms Kiri Collins, [tbmgmt@ccia.unsw.edu.au](mailto:tbmgmt@ccia.unsw.edu.au); phone 02 9385 2085.**

## 7) CAN I AND MY CHILD DECIDE IF HE/SHE SHOULD NOT PARTICIPATE OR WITHDRAW FROM THE STUDY?

Yes. Participation in this study is completely voluntary and if you decide that you do not want your child to take part, or if you decide to withdraw your child at any time, this will not affect the relationship with your doctors. Your decision will not affect the standard of care or treatment your child will receive from their health professional team and the hospital.

If you initially agree to have your child participate in the study, you may take away your permission at any time by contacting the study doctor and signing a 'revocation of consent' form. This means your child will not stay in this study and their information will no longer be collected in the registry (however, the information collected prior to that will remain recorded).

## 8) WHO SHOULD I CONTACT IF I HAVE CONCERNS ABOUT THE CONDUCT OF THIS STUDY?

This study has been reviewed and approved by the Hunter New England Human Research Ethics Committee  
Reference No: 18/04/18/4.03

If you have concerns about your child's rights as a participant in this research, or if you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, you may contact:

Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305  
Telephone: (02) 4921 4950  
Email: [hnehrec@hnehealth.nsw.gov.au](mailto:hnehrec@hnehealth.nsw.gov.au)

This project has also been authorised to be conducted at The Sydney Children's Hospital, Randwick. If you have any concerns about the conduct of this study at this site please do not hesitate to contact the Research Governance Officer on (02) 9845 3011 and quote [SSA/18/SCHN/407].

If you would like your child to take part in the study, please sign the consent form at the end of this information sheet. This information sheet is for you to keep. We will also give you a copy of the signed consent form.

Patient's Name (Family, Given):  
 MRN:  
 MRD STUDY NUMBER:



## Parent/ Guardian Consent Form

### Minimal Residual Disease (MRD) Testing and Related Research on Leukaemia

**Please read the information below carefully. If you decide that you would like your child to have MRD testing please sign in the space provided below. Please also tick either Yes or No in the check boxes to indicate if you agree to help with our research.**

I confirm that:

- I have read and understood the information sheet and I have had my questions answered.
- I am aware that I should retain a copy of the Information Sheet and Consent Form for future reference.
- I understand that, for clinical reasons, my doctor has requested MRD tests for my child at the Children's Cancer Institute. These tests will involve bone marrow, blood or other samples being collected and some personal information being securely stored. I know that MRD reports will be sent to my child's doctor who is responsible for clinical decisions.
- I know that any leftover samples may be stored in a tissue bank and used for future research without further consent.
- I know that Children's Cancer Institute staff may contact my hospital or another registry for information on my child's health.
- I understand that the chances of research finding genetic changes that may affect other members of our family are very low, but in case this happens, I can decide if I want to be told about it.
- I am aware the Leukaemia registry will include detailed information about patients with leukaemia and can be accessed by doctors and scientists for research to benefit future patients.
- I understand that I can choose not to participate in research or the registry. I will be free to withdraw at any time and this decision will not affect my child's treatment or our relationship with our doctors.
- I am signing this consent form voluntarily to indicate my decision to participate in these activities.

I, \_\_\_\_\_ agree to MRD testing for my child \_\_\_\_\_

• I agree to have my child's leftover samples stored and used for future research	<input type="checkbox"/> Yes <input type="checkbox"/> No
• I agree to the hospital, Children's Cancer Institute and other registries sharing non-confidential information on my child's health and treatments for use in research	<input type="checkbox"/> Yes <input type="checkbox"/> No
• I agree that my child's non-confidential information can be included on the Leukaemia registry for research	<input type="checkbox"/> Yes <input type="checkbox"/> No
• I would like to be contacted in the unlikely event of a genetic finding that may have an impact on my child or other members of our family	<input type="checkbox"/> Yes <input type="checkbox"/> No

**Signature of Parent/Guardian**

**Please PRINT name**

**Date**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**PATIENT AGED 16 – 18 YEARS OLD**

**Signature of Patient**

**Please PRINT name**

**Date**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Signature of Interpreter (if applicable)**

**Please PRINT name**

**Date**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Patient's Name (Family, Given):  
MRN:  
MRD STUDY NUMBER:



## Revocation of Consent Minimal Residual Disease (MRD) Testing and Related Research on Leukaemia

- I hereby WITHDRAW my consent for inclusion of my child on the Leukaemia Registry at the Children's Cancer Institute. I understand that such withdrawal WILL NOT make any difference to my relationship with the hospital or medical attendants.
- I hereby WITHDRAW my consent for future research on samples collected from my child. I understand that such withdrawal WILL NOT make any difference to my relationship with the hospital or medical attendants.
- I hereby WITHDRAW my consent for the future provision of information about my child's health. I understand that such withdrawal WILL NOT make any difference to my relationship with the hospital or medical attendants.

Name of Patient: \_\_\_\_\_

Date of Birth: \_\_\_\_\_

Signature of Parent/Guardian

Please PRINT name

Date

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**PATIENT AGED 16 – 18 YEARS OLD**

Signature of Patient

Please PRINT name

Date

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Signature of Interpreter (if applicable)

Please PRINT name

Date

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**The section for Revocation of Consent can be given to your child's doctor for forwarding to:**

The Scientific Services Manager,  
Children's Cancer Institute,  
C25 Lowy Cancer Research Centre, UNSW,  
PO Box 81, Randwick, NSW 2031, Australia.  
Fax 02 9662 6584