PARTICIPANT INFORMATION SHEET AND CONSENT FORM

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

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WHAT IS THIS INFORMATION/CONSENT FORM ABOUT?

Your hospital doctor has requested that the Children's Cancer Institute performs some tests to measure minimal residual disease (MRD). The results from MRD testing are important for making decisions about your 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 you, your MRD results combined with information on your progress and/or research on your leftover samples, could help people 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. It also provides information so you can decide if you wish to be a part of our research, aimed at benefiting patients in the future, through three different ways. You may agree to have your MRD test results and information on a leukaemia registry and/or agree to storage and future use of your leftover samples. For either of these options you may agree to us receiving future updates on your 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 world-wide 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 patient 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 doctor, and clinical trial centres if applicable, and your doctor has the responsibility for interpreting these results for you. **If you have questions at any time about MRD testing, your hospital doctor will be happy to answer them.**

Your MRD test(s) will be specific for your leukaemia, so we need to keep records for any future requests for MRD testing. We will record your name, date of birth, diagnosis, hospital, medical record number, any clinical trial, your hospital consultant and keep a copy of the consent form in a database at the Children's Cancer Institute. We will also record your 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.

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 people at higher risk of treatment failure or toxicity. We would like your permission to include your MRD results and to collect and include other information from your hospital doctor in the registry. The registry will not include confidential information. It would include your age, gender, any known high risk factors, biological and genetic features of your leukaemia, MRD results, information on your treatments and your 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 LEFTOVER MRD SAMPLES?

After your 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 samples will not be sold and will only be used for:
1) Tests that your 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 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 PRIVACY BE PROTECTED IN THE RESARCH ACTIVITIES?

The Leukaemia registry will not include confidential information such as your name, date of birth or other personal information. Your 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 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 you will not be identified by name.

5) WILL I BENEFIT FROM THE RESEARCH?

Most research will not show results for a considerable period and it is unlikely you will receive any direct medical value. You will not receive money or other forms of compensation for your 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 children 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 can be informed of this information by your treating doctor or GP who is listed on your medical records charts.

6) HOW IS THE INFORMATION FOR RESEARCH KEPT CURRENT?

Researchers who use the MRD registry information or who use your leftover samples may ask for up-to-date information on your health. If you give consent, then Children's Cancer Institute staff from the MRD group or Tissue Bank may request your hospital doctor or clinical trial co-ordinator or another registry for this information. Only authorised staff will have access to your name and other personal details. Your health information will be recorded using MRD, trial or registry numbers to preserve your privacy. In rare cases, more information may be needed from you 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; phone 02 9385 2085.

7) CAN I DECIDE TO 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 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

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 to take part in 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:

Participant 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 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 me 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 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 health.
- I understand that the chances of research finding genetic changes that may affect other members of my 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 treatment or my relationship with my doctors.
- I am signing this consent form voluntarily to indicate my decision to participate in these activities.

I, _____ agree to MRD testing

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

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 on the MRD 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 my collected samples. 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 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 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 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